

abbvie



# **Irish Society for Rheumatology Spring Meeting 2015**



**27 March 2015  
Hotel Kilkenny**

Brochure kindly sponsored by MSD







IN DMARD-IR AND TNF-IR RA PATIENTS,  
WHEN COMBINATION WITH MTX IS NOT AN OPTION...

THINK  
ROACTEMRA<sup>1</sup>

Now available in  
Subcutaneous (SC)

**RoACTEMRA<sup>®</sup>**  
tocilizumab

ABRIDGED PRESCRIBING INFORMATION. (For full prescribing information, refer to the Summary of Product Characteristics [SmPC])

RoActemra® (tocilizumab) 20mg/ml Concentrate for Solution for Infusion (RoActemra IV) and RoActemra® 162mg solution for injection in pre-filled syringe (RoActemra SC)

Indications: ABRIDGED PRESCRIBING INFORMATION. (For full prescribing information, refer to the Summary of Product Characteristics [SmPC]). RoActemra® (tocilizumab) 20mg/ml Concentrate for Solution for Infusion (RoActemra IV) and RoActemra® 162mg solution for injection in pre-filled syringe (RoActemra SC)

Indications: **RoActemra SC:** In combination with methotrexate (MTX), for the treatment of adult patients with moderate to severe active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. **RoActemra IV:** In combination with MTX for the treatment of (i) severe, active and progressive RA in adults not previously treated with MTX, (ii) adult patients with moderate to severe active RA who have had an inadequate response or intolerance to one or more DMARDs or TNF antagonists, (iii) active systemic juvenile idiopathic arthritis (sJIA) in patients  $\geq 2$  years of age, who responded inadequately to previous therapy with MTX, RoActemra IV/SC can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate for all indications. RoActemra IV/SC has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with MTX for the treatment of adult RA patients. **Dosage & Administration:** Treatment should be initiated by HCPs experienced in the diagnosis and treatment of RA, sJIA or pJIA and all patients should be given the Patient Alert Card. **RA: RoActemra IV:** 8mg/kg diluted to a final volume of 100ml, given once every 4 weeks by IV infusion over 1 hour. For patients  $>100$ kg, doses  $>800$ mg per infusion are not recommended. No data on doses above 1.2g. **RoActemra SC:** 162mg once every week, irrespective of weight. Patients may self-inject after training. Rotate injection site frequently. **sJIA (RoActemra IV only):** Patients  $<2$  years of age – no data. Patients  $\geq 2$  years, 8mg/kg diluted to final volume of 100ml for patients  $\geq 30$ kg or 12mg/kg diluted to final volume of 50ml for patients  $<30$ kg once every 2 weeks by IV infusion over 1 hour. Clinical improvement generally seen within 6 weeks of starting RoActemra; reconsider continued therapy if no improvement. **pJIA (RoActemra IV only):** Patients  $<2$  years of age – no data. Patients  $>2$  years of age, 8mg/kg diluted to final volume of 100ml for patients  $\geq 30$ kg or 10 mg/kg diluted to final volume of 50ml for patients  $<30$ kg once every 4 weeks by IV infusion over 1 hour. Clinical improvement generally seen within 12 weeks of starting RoActemra; reconsider continued therapy if no improvement. For pJIA/sJIA: check patient's weight at each visit. **Dose adjustments:** For raised liver enzymes, modify concomitant DMARDs if appropriate, reduce or interrupt dose of RoActemra; for low absolute neutrophil count (ANC) or low platelet count reduce or interrupt RoActemra. In some instances discontinue RoActemra (see SmPC). **Special Populations:** No data available for RoActemra SC in patients  $<18$  years of age. Closely monitor renal function in patients with moderate to severe renal impairment. No data in patients with hepatic impairment. No dose adjustments in patients  $>65$  years. **Contraindications:** Hypersensitivity to any component of the product; active, severe infections. **Warnings & Precautions:** Cases of serious infections (sometimes fatal) have been reported; interrupt therapy until controlled. Caution in patients with recurring/chronic infections, or other underlying conditions (e.g. diverticulitis, diabetes and interstitial lung disease) which predisposes to infection. Patients and parents/guardians of sJIA and pJIA patients should contact their HCP when symptoms suggestive of infection appear. Screen for latent TB and treat if required prior to starting therapy. Patients to seek medical attention if sign/symptoms suggestive of TB occur during or after treatment. Viral reactivation (e.g. hepatitis B) reported with biologic therapies. Caution in patients with a history of intestinal ulceration or diverticulitis. Serious hypersensitivity reactions, including anaphylaxis, reported and may be severe and potentially fatal in patients who have experienced hypersensitivity reactions during previous treatment even if they have received premedication with steroids and anti-histamines. If an anaphylactic reaction or other serious hypersensitivity/serious infusion related reaction occurs, permanently discontinue RoActemra. Use with caution in patients with active hepatic disease/impairment. Not recommended in patients with baseline ALT or AST  $> 5 \times$  ULN; caution in patients with ALT or AST  $> 1.5 \times$  ULN (see SmPC). Risk of neutropenia may increase in patients previously treated with TNF antagonist. Continued therapy not recommended in patients with ANC  $< 0.5 \times 10^9/l$  or platelet count  $< 50 \times 10^9/l$ . Do not initiate RoActemra treatment where ANC is below  $2 \times 10^9/l$ . Caution in patients with low platelet count; monitor neutrophils and platelets in RA, sJIA and pJIA patients according to SmPC. Elevations in lipid parameters seen; if elevated, follow local guidelines. Be vigilant for symptoms of new-onset central demyelinating disorders. Immunomodulatory medicines may increase malignancy risk in RA patients. Live and live attenuated vaccines should not be given concurrently (see SmPC). Not recommended for use with other biological agents. Macrophage activation syndrome (MAS), a serious life-threatening disorder, may develop in sJIA patients – RoActemra not studied in patients during an active MAS episode. Trade name should be clearly recorded in patient file to improve traceability of biological medicines. **Drug Interactions:** Studies only performed in adults. Monitor patients taking medicines individually adjusted and metabolised via CYP450 3A4, 1A2 or 2C9 when starting/stopping RoActemra, as doses may need to be increased to maintain therapeutic effect. Effects of tocilizumab on CYP450 enzyme activity may persist for several weeks after stopping therapy (refer to SmPC for further details on cytochrome CYP450 and other drug interactions).

**Fertility, Pregnancy & Lactation:** Women should use contraception during and up to 3 months after treatment. No adequate data from use in pregnant women. Animal study showed increased risk of spontaneous abortion/embryo-fetal death at high dose. RoActemra should not be used during pregnancy unless clearly necessary. No lactation data in humans. A decision on whether to continue/discontinue breastfeeding or RoActemra therapy should be made taking into account the relative benefits to the child and mother. Refer to SmPC. **Effects on ability to drive and use machines:** RoActemra has minor influence on the ability to drive and use machines (dizziness). **Undesirable Effects:** Prescribers should consult SmPC for full details of ADRs. **RoActemra IV:** RA: ADRs occurring in RoActemra trials: Very Common ( $\geq 1/10$ ): upper respiratory tract infections, hypercholesterolaemia. Common ( $\geq 1/100 - <1/10$ ): cellulitis, pneumonia, oral herpes simplex, herpes zoster, abdominal pain, mouth ulceration, gastritis, rash, pruritus, urticaria, headache, dizziness, hepatic transaminases increased, weight increased, total bilirubin increased, hypertension, leucopenia, neutropenia, peripheral oedema, hypersensitivity reactions, conjunctivitis, cough and dyspnoea. **sJIA:** ADRs were similar to those seen in RA patients. Serious infections of varicella and otitis media reported (in addition to infections for RA). Hypersensitivity reactions requiring treatment discontinuation occurred in  $<1\%$  of patients. Other events occurring within 24 hours of infusion (16% of patients) included rash, urticaria (considered serious), diarrhoea, epigastric discomfort, arthralgia and headache. Decreased IgG levels during therapy. **pJIA:** ADRs were similar to those seen in RA and sJIA patients. Nasopharyngitis, headache, nausea, and decreased neutrophil count more frequently reported in the pJIA population. The incidence of infections leading to dose interruptions was numerically higher in patients weighing  $<30$ kg, the rate of serious infections was also higher in these patients. 20.2% experienced an infusion reaction within 24 hours of infusion. **RoActemra SC:** The safety and immunogenicity was consistent with the known safety profile of IV. Injection site reactions (including erythema, pruritus, pain and haematoma) were mild to moderate in severity. **Serious or Potentially Serious:** serious infections, active tuberculosis, invasive pulmonary infections, interstitial lung disease (including pneumonitis and pulmonary fibrosis), GI perforations (as complications of diverticulitis), serious hypersensitivity reactions, Stevens-Johnson syndrome. See SmPC section 4.8 for instructions on the reporting of Suspected Adverse Reactions. **Legal Category:** Subject to medical prescription which may not be renewed (A). **Presentations & Marketing Authorisation Numbers:** 80mg of tocilizumab in 4ml (20mg/ml) pack of 1 (EU/1/08/492/001); 200mg of tocilizumab in 10ml (20mg/ml) pack of 1 (EU/1/08/492/003); 400mg of tocilizumab in 20ml (20mg/ml) pack of 1 (EU/1/08/492/005); 162mg tocilizumab solution for injection (in 0.9ml) in pre-filled syringe (EU/1/08/492/007).

**Marketing Authorisation Holder:** Roche Registration Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom. RoActemra is a registered trade mark. Further information is available from Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24. Telephone: (01) 4690700. Fax: (01) 4690791. **Date of Preparation:** March 2015.

**References:** 1. Nisar MK et al. The role of tocilizumab monotherapy in the management of rheumatoid arthritis: a review. Int. J. Clin. Rheumatol. (2012) 7(1): 9-19.

**Date of item:** March 2015. IE/RACTE/0315/0006

Roche





## Welcome Message from the ISR President Professor David Kane

### Dear Colleagues and Friends

I am delighted to welcome you all to our Spring meeting in the medieval city of Kilkenny. I am very grateful to our Academic team in the South East namely Donncha O'Gradaigh, Claire Sheehy and Darragh Foley-Nolan for organising a most interesting programme. The focus of the programme is very much on pain and its many facets. While the specialty of rheumatology has flourished through the major advances in treating inflammation many other conditions such as osteoarthritis and fibromyalgia have very limited therapy. For many of our patients pain remains the most difficult to treat of symptoms and this meeting is a timely opportunity to reflect on that and look for new answers. I look forward to welcoming and hearing all of the fine speakers who have agreed to present at our meeting and hope to gain some new insights into the causes and treatment of pain.

I will continue during my Presidency to deliver the agenda you have given me through our members' survey. This will focus on the areas of undergraduate training, postgraduate training and the development of shared clinical and research resources and networks.

The ISR Board will look at ways to innovate and reinvigorate our annual meetings this year and any suggestions from members are always welcome. Did you encounter a vasculitis patient after Prof Jayne's lecture last year and wish you could recall all those excellent tips on vasculitis? As part of this last year's meeting the key speakers were recorded and this is now available for members to peruse and even use for their own in-house education sessions. We will look for members' feedback to see how this develops.

As promised this year we will launch the O'Connor medal in Rheumatology for medical undergraduates. A proposal will soon be brought to members to implement the Rheumatology Curriculum in a web-based format whereby each member could deliver a small part of the entire curriculum which could then be made available to all undergraduates in Ireland. In postgraduate training we already have an excellent clinical programme but we will build on skills course such as in ultrasound and in MRI interpretation, synovial fluid analysis and capillaroscopy.

The ISR strongly endorses the development of national registries such as the AS register being delivered by Dr Barry O'Shea and the proposed ISR Biologics Registry led by Prof Gerry Wilson. We have allocated a session to hear an update on the ISRBR and to allow all members to have their say. Can I encourage you to get involved with these initiatives and to discuss with Barry and Gerry at the meeting.

Similarly it is my intention to hold a forum on electronic patient records later this year as I feel the specialty must take control of its own data if we are to push for more services for our patients. It's going to be a busy 2015 but I only get to do this once, so why not!!

Finally, I welcome our colleagues in IRHPS and I hope that they will have a memorable conference and I acknowledge our gratitude to our colleagues in Industry for their continued support without which these excellent and important meetings would not happen.

Above all enjoy the educational and catching up with colleagues.

**Professor David Kane,**  
ISR President



When MTX alone is not enough...

# Trust in HUMIRA: an unmatched legacy

**10 years**

of efficacy data for RA\* in label<sup>1</sup>

**10 indications**

The most of any self-administered biologic<sup>1,6</sup>

More than

**843,800 patients**

currently treated worldwide<sup>2</sup>

—In more than **85 countries**<sup>3</sup>

More than

**17 years**

of clinical trial experience, beginning with RA<sup>4,5</sup>

More than

**23,000 patients**

in global clinical studies<sup>5</sup>

**71 clinical trials** in  
the largest published global  
safety analysis for an anti-TNF,  
**36** in RA alone<sup>5</sup>

**HUMIRA (adalimumab) 40mg solution for injection in pre-filled pen or pre-filled syringe and Humira 40mg/0.8ml solution for injection for paediatric use. Refer to Summary of Product Characteristics for full information. Presentation:** Each 0.8ml single dose pre-filled pen, pre-filled syringe or vial contains 40mg of adalimumab. **Indications:** Rheumatoid arthritis (RA): In combination with methotrexate (MTX) is indicated for the treatment of moderate to severe, active RA in adult patients with inadequate response to disease-modifying and/or anti-rheumatic drugs (DMARDs) including MTX. Also indicated for the treatment of severe, active and progressive RA in adults not previously treated with MTX. Can be given as monotherapy in case of intolerance to or when continued treatment with MTX is inappropriate. Humira has been shown to reduce the rate of progression of joint damage on X-ray and to improve physical function, in combination with MTX. Polyarticular juvenile idiopathic arthritis (pJIA): In combination with MTX for the treatment of active pJIA. In patients from the age of 2 years with inadequate response to one or more DMARDs, or as monotherapy in case of intolerance to or when continued treatment with MTX is inappropriate. Enthesitis-related arthritis (ERA): Treatment of active enthesitis-related arthritis in patients from 6 years of age with inadequate response to, or intolerance of, conventional therapy. Psoriatic arthritis (PsA): Treatment of active and progressive PsA in adults with inadequate response to conventional therapy. Humira has been shown to reduce the rate of progression of peripheral joint damage on X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function. Ankylosing spondylitis (AS): Treatment of adults with severe active AS with inadequate response to conventional therapy. Axial spondyloarthritis non-radiographic (re-axSpA): Treatment of adults with severe axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to, nonsteroidal anti-inflammatory drugs (NSAIDs). Crohn's disease (CD): Treatment of moderate to severe, active CD, in adult patients not responding despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant, or who are intolerant to or have medical contraindications for such therapy. Pediatric Crohn's disease: Treatment of severe active Crohn's disease in paediatric patients (from 6 years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and an immunomodulator, or who are intolerant to or have contraindications for such therapies. Psoriasis (Ps): Treatment of moderate to severe chronic plaque psoriasis in adult patients not responding to or contraindicated for, or are intolerant to other systemic therapy including cyclosporine, MTX or PUVA. Ulcerative colitis (UC): Treatment of moderate to severe active UC in adult patients with an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or contraindicated for such therapies. **Dosage and administration:** Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of the condition. Patients should be given the special alert card. After proper injection training patients may self-inject, subject to physician approval and appropriate medical follow-up. During treatment other concomitant therapies should be optimised. RA, PsA, AS or re-axSpA: 40mg administered every other week as a single dose via subcutaneous injection. RA, MTX should be continued. In monotherapy some patients who experience a decrease in their response to Humira may benefit from an increase to 40mg every week. There may be a need for dose interruption, e.g. before surgery or if serious infection occurs. Re-introduction of Humira after discontinuation for 70 days or longer resulted in the same magnitude of clinical response and similar safety profile as before dose interruption. pJIA: Age 2 to 12 years: 24mg/m<sup>2</sup> body surface area to a maximum single dose of 20mg (for patients aged 2-4) and up to a maximum single dose of 40mg (for patients aged 4-12) administered every other week. The volume for injection is based on the patient's height and weight (see SmPC for height and weight dosing chart). For patients from 13 years: 40mg administered every other week regardless of body surface area. ERA: Age 6 years and older: 24mg/m<sup>2</sup> body surface area up to a maximum single dose of 40mg administered every other week. The volume for injection is based on the patient's height and weight (see SmPC). For RA, pJIA, PsA, AS and re-axSpA, available data suggest that the clinical response is usually achieved within 12 weeks of treatment. Continued therapy should be carefully reconsidered in a patient not responding within this time period. CD: Adults: Induction dose of 80mg at Week 0 followed by 40mg at Week 2. For a more rapid response, 160mg at Week 0 (dose can be administered as four injections in one day or as two injections per day for two consecutive days), 80mg at Week 2, can be used. Note that the risk for adverse events is higher during induction. After induction, the dose is 40mg every other week. If a patient has stopped Humira and signs and symptoms of disease recur, Humira may be re-administered. There is little experience from re-administration after more than 8 weeks since the previous dose. During maintenance treatment, corticosteroids may be tapered in accordance with clinical practice guidelines. Patients experiencing a decrease in their response may benefit from an increase in dosing frequency to 40mg every week. Patients who have not responded by Week 4 may benefit from continued maintenance therapy through Week 12 and should be carefully reconsidered in a patient not responding within this time period. Pediatric CD patients: <40kg: Induction dose of 40mg at Week 0 followed by 20mg at Week 2. In case of need for a more rapid response to therapy, the regimen 80mg at Week 0 (dose can be administered as two injections in one day), 40mg at Week 2, can be used with the awareness that the risk for adverse events is higher during induction. After induction treatment, the recommended dose is 20mg every other week. Some patients who experience insufficient response may benefit from an increase in dosing frequency to 40mg every week. Pediatric CD patients >40kg: For induction dose double the dose regimen for those patients <40kg. Continued therapy should be carefully considered in a subject not responding by week 12. Ps: Adult: Induction dose of 80mg at week 0, followed by 40mg subcutaneously given every other week from week 1. Continued therapy beyond 16 weeks should be carefully reconsidered in a patient not responding within this time period. UC: Adults: Induction dose of 160mg at week 0 (dose can be administered as four injections in one day or as two injections per day for two consecutive days) and 80mg at week 2. After induction treatment, the dose is 40mg every other week. During maintenance treatment, corticosteroids may be tapered in accordance with clinical practice guidelines. Patients experiencing a decrease in their response may benefit from an increase in dosing frequency to 40mg every week. Available data suggest that clinical response is usually achieved within 2-8 weeks of treatment. Therapy is not recommended in patients failing to respond within this time period. **Contraindications:** Active TB or other severe infections such as sepsis, and opportunistic infections moderate to severe heart failure (NYHA class III/IV) and hypersensitivity to adalimumab or any of the excipients. **Precautions and Warnings:** In order to improve traceability of biological medicinal products, the trade name and the batch number of the administered product should be clearly recorded. Infections: Patients taking TNF-antagonists are more susceptible to serious infections especially if they have impaired

lung function. Patients must be monitored for infections, including tuberculosis, before, during and for 4 months after treatment. Treatment should not be initiated in patients with active, infections until they are controlled. The risks and benefits of treatment should be considered prior to initiating therapy in patients who have been exposed to tuberculosis or endemic mycoses. New infections during treatment should be evaluated and monitored closely. Treatment should be discontinued for new serious infection or sepsis and treated appropriately. Exercise caution when treating patients with a history of recurring infections or who are predisposed to infections. Serious infections, including those with hospitalisation or death have been reported in patients receiving treatment. Tuberculosis: Consult SmPC for details. Reactivation and new onset TB, both pulmonary and extra pulmonary (disseminated) have been reported. Before initiation of therapy all patients must be screened for both active or inactive (latent) TB. If active TB is diagnosed Humira must not be initiated. If latent TB is suspected, a physician with appropriate expertise should be consulted and local treatment recommendations for prophylaxis followed prior to initiation of Humira. Despite prophylaxis TB reactivation has occurred on Humira. Other opportunistic infections: Opportunistic infections have been observed in patients receiving Humira. In patients with signs and symptoms of such infections, Humira should be discontinued. Diagnosis and administration of empiric antifungal therapy in these patients should be made in consultation with a physician with appropriate expertise. Hepatitis B Reactivation: Reactivation has occurred in chronic carriers (i.e. surface antigen positive) tested for HBV infection before initiating treatment. Carriers should have a consultation with a specialist physician. HBV carriers should be closely monitored for signs and symptoms of active HBV infection throughout therapy and for several months following termination of Humira. If reactivation occurs discontinue treatment and initiate appropriate anti-viral and supportive treatment. Neurological events: Humira has a rare association with new onset or exacerbation of clinical symptoms and/or radiographic evidence of central and peripheral nervous system demyelinating disease. Caution is advised when considering Humira in patients with pre-existing or recent onset central or peripheral nervous system demyelinating disorders. Multiple reactions: Reports of serious allergic reactions including anaphylaxis have been received. If an anaphylactic reaction or other serious allergic reaction occurs, Humira should be discontinued immediately and appropriate therapy initiated. Malignancies and lymphoproliferative disorders: A possible risk of malignancy, including lymphoma and leukaemia, in patients including children and adolescents treated with TNF-antagonists cannot be excluded. All patients, and in particular those with a history of extensive immunosuppression or PNA treatment, should be monitored for non-melanoma skin cancer prior to and during Humira therapy, caution in COPD patients, as well as in patients with increased risk of malignancies due to heavy smoking. The potential risk with the combination of azathioprine or 6-mercaptopurine and Humira should be carefully considered (hepatosplenic T-cell lymphoma has occurred). A risk for the development of hepatosplenic T-cell lymphoma in patients treated with Humira cannot be excluded. Caution should be exercised in considering Humira treatment in patients with a history of malignancy. The risk for developing dysplasia or colon cancer is unknown. UC patients and those with a prior history of dysplasia or colon carcinoma should be screened for dysplasia before therapy and throughout their disease course. This evaluation should include colonoscopy and biopsies per local recommendations. Haematologic reactions: Adverse events of the haematologic system have been reported with Humira. Patients should be advised to seek immediate medical attention if they develop signs and symptoms of blood dyscrasias. Vaccinations: Patients on Humira may receive concurrent vaccinations, except for live vaccines. Paediatric patients should be brought up to date with all immunisations prior to initiating Humira (see also fertility, pregnancy and lactation section). Congestive heart failure: See contraindications. Caution is advised in mild heart failure (NYHA class I/II) and treatment discontinued in patients who develop new or worsening symptoms of congestive heart failure. Autoimmune processes: Autoimmune antibodies may form. Discontinue treatment if development of a lupus-like syndrome with positive antibodies against double-stranded DNA. Surgery: The long half life of Humira should be considered when a surgical procedure is planned. Patients should be monitored for infections. Small bowel obstruction: Failure to respond to treatment for CD may indicate the presence of fixed fibrotic stricture that may require surgical treatment. Data suggests that Humira does not worsen or cause strictures. Other people: Serious infections were higher in patients over 65 years of age some of whom had fatal outcomes. Consider risk of infection. **Interactions:** Combination of adalimumab with other biologic DMARDs (e.g. anakinra and abatacept) or other TNF-antagonists is not recommended. **Fertility, pregnancy and lactation:** Treatment is not recommended during pregnancy. Women of childbearing potential should use adequate contraception and continue its use for at least five months after the last Humira treatment. Administration of live vaccines to infants exposed to adalimumab in utero is not recommended for 5 months following the mother's last adalimumab injection during pregnancy. Women must not breast-feed for at least five months after the last Humira treatment. **Driving and machinery:** Humira may have a minor influence on the ability to drive, cycle or use machines. **Side Effects:** The most commonly reported side effects are infections, leucopenia, anaemia, lipids increased, headache, abdominal pain, nausea and vomiting, elevated liver enzymes, rash (including exfoliative rash), musculoskeletal pain, injection site reaction. **Prescribers should consult the SmPC for the other less commonly reported side effects.** Serious, including fatal, side effects have been reported including infections/sepsis, intestinal perforation, opportunistic infections, TB, endemic mycoses, demyelinating disease, malignancies including lymphoma (including hepatosplenic T-cell lymphoma), leukaemia and skin cancer (including melanoma and merkel cell carcinoma), cytopenias, worsening heart failure, myocardial infarction, pulmonary embolism, pleural effusion, pulmonary fibrosis, cerebrovascular accident, interstitial lung disease, Stevens-Johnson syndrome, angioedema, anaphylaxis, sarcoidosis, hepatitis, liver failure and worsening of symptoms of dermatomyositis. **Overdose:** No dose-limiting toxicity was observed during clinical trials. The highest dose level evaluated has been multiple intravenous doses of 10 mg/kg (approximately 15 times the recommended dose). **Legal Category:** POM. **Marketing Authorisation Numbers/Presentations:** Vial: EU/1/03/256/001; 1 pack contains 2 cartons each containing 1 single use vial and empty sterile injection syringe, needle and vial adapter, Pre-filled Syringe: EU/1/03/256/003; Each carton contains 2 single use pre-filled syringes in a blister. Pre-filled Pen: EU/1/03/256/008; Each carton contains 2 single use pre-filled pens in a blister. Further information is available from AbbVie Limited, Block B, Lilly Valley Office Campus, Quarryville, Co. Dublin. HCPs are asked to report any suspected adverse reactions via IPRa pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: mcsafesys@hpra.ie. Suspected adverse reactions should also be reported to AbbVie Limited on 01-4287900. Date of revision of PI: September 2014/PI/256/012

TNF=tumour necrosis factor. \* In moderate to severe RA. <sup>1</sup> In adult moderate to severe RA. First patient dosed in April 1997.

**References:** 1. HUMIRA [summary of product characteristics]. AbbVie Ltd. 2. Data on File, AbbVie. 3. Data on File, AbbVie. 4. Data on File, AbbVie. 5. Burmester GR, Panaccone R, Gordon KB, et al. Adalimumab: long-term safety in 23 458 patients from global clinical trials. *Ann Rheum Dis*. doi:10.1136/annrheumdis-2011-201244. 6. Data on File, AbbVie.

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Date of Preparation: February 2015

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**PROGRAMME ISR Spring Meeting**  
**HOTEL KILKENNY, Friday 27th March 2015**

9-00am	<b>Coffee and Meet The Industry</b>
9.45am	<b>Welcome</b> ISR President Prof David Kane Chair: Dr Claire Sheehy
10.00am	<b><i>“Low Back Pain In Primary Care – Effectiveness of Group Based Physiotherapy Care”</i></b> Susan Murphy Phd, University Hospital Waterford
10.30am	<b><i>“Hypermobility And Ehler-Danlos-UCLH Experience of An Exploding Population”</i></b> Dr Nicola Ambrose Consultant Rheumatologist University College Hospital London
11.00am	<b><i>“Mtx Irreversible Bone-Marrow Toxicity, Case Report and Discussion”</i></b> Dr Donncha O’Gradaigh and Una Martin CNS University Hospital Waterford
11.15am	<b>Coffee Break &amp; Meet The Industry</b>
11.45am	Chair: Dr Donncha O’Gradaigh  <b><i>“Development of Biological Registers in Ireland”</i></b> Prof Gerry Wilson St. Vincent’s University Hospital, Dublin 4
12.15pm	<b>Young Investigator Award</b> Dr Lorna Gallagher Tallaght Hospital, Dublin 24
12.30pm	<b><i>“Neuroplasticity and Pain”</i></b> Dr David Hevey Phd Psychology Dept., Trinity College, Dublin
1.20pm	<b>Lunch &amp; Meet The Industry</b>  Chair: Dr Darragh Foley-Nolan
2.15pm	<b><i>“Mindfulness and Pain Control”</i></b> Fidelma Farley, Oscailt Centre, Ranelagh, Dublin 6
2.45pm	<b><i>“Update on the Pain Physician’s Treatment Approach”</i></b> Dr Connail McCrory, St. James’s Hospital, Dublin 8
3.15pm	<b><i>“Psychorheumatology”</i></b> Dr Siobhan MacHale, Beaumont Hospital, Dublin 9
4.00pm	<b>Questions and Close</b>





## ...Committed to our future





## Academic Organisers

### Dr Donncha O'Gradaigh

University Hospital Waterford

Dr O Gradaigh trained in Dublin and Waterford before moving to the UK for specialist training in Rheumatology. He returned to Ireland in 2004 as a consultant rheumatologist at Waterford Regional Hospital, now University Hospital Waterford. Initially establishing early arthritis and biologic therapy clinics, he has special interests in bone disease, sports and exercise medicine and in musculoskeletal ultrasound. He has established a Physiotherapy-delivered shoulder ultrasound services. His expertise in osteoporosis developed during his PhD research in bone biology. He set up the DXA and Fracture Liaison Service at the hospital. Research interests include shared decision-making and evidence-based health service planning, currently pursuing an MSc at the renowned Centre for Evidence-Based Medicine at Oxford.



### Dr Claire Sheehy

University Hospital Waterford

Dr Claire Sheehy MD has been a consultant rheumatologist in University Hospital Waterford since 2012. She trained in TCD and after completing basic training, undertook her MD project in Connolly Hospital. This was a study of remission induction and maintenance in early RA, following withdrawal of biologic therapy. Following SpR training, she undertook a vasculitis and connective tissue disease fellowship in Norfolk and Norwich University Hospital. Her main areas of interests are teaching, RA and connective tissue disease



## ISR Autumn Meeting 2015

24th and 25th September 2015  
Killashee House Hotel, Naas, Co. Kildare



## Speakers

### Dr Nicola Ambrose

University College Hospital London

Dr Nicola Ambrose joined the University College London Hospital (UCLH) team as a consultant rheumatologist in 2014. Her clinical interests include adolescent and adult rheumatology, vascular biology, connective tissue disorders and chronic pain.

She was awarded a Clinical Research Fellowship from the Royal College of Physicians Ireland and subsequently a Junior Fellowship from Arthritis Research UK, to undertake a PhD at Imperial College London. Her PhD was awarded for research into abnormal inflammation in Behçet's Syndrome. She then moved to UCLH in 2013 to undertake a clinical fellowship in adolescent rheumatology (Richard Steven's Scholarship recipient), before joining the department permanently as a consultant. She holds an honorary contract at UCL and Imperial College London.

She is regularly involved in teaching medical students, junior doctors and allied health professionals, and has written numerous publications. Her research interests are: Adolescent Rheumatology and Vascular Biology.



### Prof Gerry Wilson

University College, Dublin

Professor Gerry Wilson graduated in Medicine from Queen's University Belfast. He was awarded an ARC Clinical Fellowship for a PhD thesis which he undertook at the University of Sheffield. He was subsequently awarded an ARC Copeman Fellowship for research at Stanford University. He was appointed Professor in Rheumatology and Honorary Consultant Rheumatologist at the University of Sheffield Medical School and Sheffield Teaching Hospitals NHS Foundation Trust where he was Head of the Sheffield EULAR Centre of Excellence for Rheumatology. Prof Wilson was appointed to the Arthritis Ireland/UCD Chair of Rheumatology in 2013. Research interests include genetic and epigenetic influences in RA.



### Dr David Hevey

Trinity College Dublin

After graduating with first class honours degrees in both my undergraduate (B.A. Psychology (Hons), UCD 1994) and postgraduate (M.A. Applied Psychology, UCD, 1995) studies, I completed my HRB-funded PhD in Trinity College Dublin (1999).

After working in Beaumont Hospital and the Royal College of Surgeons in Ireland, I joined the School of Psychology, TCD, in February 2002.

My internationally-recognised research programme focuses on the application of psychology to enhance Quality of Life (QOL) and adjustment for people with chronic illness. My research receives significant grant awards and is consistently published in the best international journals, many of which are in the top 10 of their respective fields based on current ISI rankings. I have 65 articles published or in press in peer-reviewed journals and 7







PROVEN EVIDENCE ACROSS  
ALL 3 STAGES OF axSpA<sup>1-9</sup>

SIGNIFICANT AND SUSTAINED  
IMPROVEMENTS IN DISEASE  
ACTIVITY AND FUNCTION<sup>1-9</sup>

NOT ASSOCIATED WITH  
NEUTRALISING ANTIBODIES<sup>1</sup>

# THE ENBREL WAY

ACROSS ALL STAGES OF axSpA

axSpA, Axial SpondyloArthritis

\* Enbrel is licensed for the treatment of adults with severe non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated CRP and/or MRI evidence who have had an inadequate response to nonsteroidal anti-inflammatory drugs and for the treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy.<sup>1</sup>

## ABBREVIATED PRESCRIBING INFORMATION

### Enbrel<sup>®</sup> etanercept

Before prescribing Enbrel<sup>®</sup> please refer to full Summary of Product Characteristics (SmPC). **Presentation:** Enbrel Pre-filled Syringe: Enbrel 25 mg and 50 mg solution for injection in pre-filled syringe. Each pre-filled syringe contains either 25 mg or 50 mg etanercept. Enbrel Pre-filled Pen (MYLUC<sup>®</sup>): Enbrel 50 mg solution for injection in pre-filled pen. Each pre-filled pen contains 50 mg etanercept. Enbrel Powder: Enbrel 25 mg powder and solvent for solution for injection. Each vial contains 25 mg etanercept and each pre-filled syringe contains 1 ml water for injections. Enbrel Paediatric: Enbrel 10 mg powder and solvent for solution for injection for paediatric use. Each vial contains 10 mg etanercept and each pre-filled syringe contains 1 ml water for injections. **Uses:** Adults: Moderate to severe active rheumatoid arthritis (RA), in combination with methotrexate, when response to disease-modifying anti-rheumatic drugs (DMARDs), including methotrexate (unless contraindicated), has been inadequate. Enbrel can be given as monotherapy in the case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Severe, active and progressive RA without prior methotrexate treatment. Enbrel alone or with methotrexate has been shown to reduce the rate of progression of joint damage measured by X-ray and to improve physical function. Patients with moderate to severe plaque psoriasis (PP) who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or PUVA. Active and progressive psoriatic arthritis (PsA) when response to DMARDs has been inadequate. Enbrel has been shown to improve physical function in PsA patients, and to reduce the progression rate of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of PsA. Severe active ankylosing spondylitis (AS) when response to conventional therapy has been inadequate. **Non-radiographic axial spondyloarthritis (nr-axSpA):** Treatment of adults with severe non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to nonsteroidal anti-inflammatory drugs (NSAIDs). **Children aged 2-17 years:** Juvenile idiopathic arthritis (JIA). Polyarthritis (rheumatoid factor positive or negative) and extended oligoarthritis from the age of 2 years when inadequate response to, or intolerant of methotrexate. Psoriatic arthritis from the age of 12 years when inadequate response to, or intolerant of methotrexate. Enthesitis-related arthritis from the age of 12 years when inadequate response to, or intolerant of, conventional therapy. **Children aged 6-17 years:** Chronic severe psoriasis when inadequately controlled by, or intolerant to, other systemic therapies or phototherapies. **Dosage:** By subcutaneous injection. **Adults:** RA – 25 mg twice weekly or 50 mg once weekly PP – 25 mg twice weekly or 50 mg once weekly for up to 24 weeks, or 50 mg twice weekly for up to 12 weeks followed by 25 mg twice weekly or 50 mg once weekly for a further 12 weeks if needed. Continuous therapy may be appropriate for some adult patients. Discontinue if no response after 12 weeks. For re-treatment: 25 mg twice weekly or 50 mg once weekly for up to 24 weeks. **AS, nr-axSpA and PsA – 25 mg twice weekly or 50 mg once weekly. Children aged 2-17 years:** JIA – 0.4 mg/kg (maximum per dose 25 mg) twice weekly with an interval of 3 – 4 days or 0.8 mg/kg (maximum per dose 50 mg) once weekly. Discontinuation of treatment should be considered in patients who show no response after 4 months. **Children aged 6-17 years:** Plaque psoriasis in children aged 6-17 years – 0.8 mg/kg (maximum per dose 50 mg) once weekly for up to 24 weeks. Discontinue if no response after 12 weeks. For re-treatment: 0.8 mg/kg (maximum per dose 50 mg) once weekly for up to 24 weeks.

**Contra-indications:** Hypersensitivity to any of the ingredients, sepsis or risk of sepsis, active infections. **Warnings and Precautions:** Enbrel should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA, JIA, PsA, AS, PP or Paediatric PP. Patients treated with Enbrel should be given the Patient Alert Card. Use carefully in patients predisposed to, or with history of, infection due to underlying diseases other than RA (e.g. advanced or poorly controlled diabetes) or with history of blood dyscrasias, pre-existing or predisposition to demyelinating disease or congestive heart failure. Cases of active tuberculosis have been reported, therefore all patients should be evaluated for both active and inactive TB prior to being treated with Enbrel. If active TB is diagnosed, Enbrel should not be initiated. Caution should be used when administering Enbrel to patients previously infected with hepatitis B and there have been reports of worsening hepatitis C in patients receiving Enbrel. Use with caution in patients with a history of hepatitis C. Whether treatment with Enbrel might influence the development and course of active and/or chronic infections is unknown. Concurrent administration of Enbrel and anakinra has been associated with increased risk of serious infections and neutropenia, and is therefore not recommended. In clinical studies, concurrent administration of abatacept and Enbrel resulted in increased incidences of serious adverse events, and is therefore not recommended. Use caution when considering combination therapy with DMARDs other than methotrexate. Reports of various malignancies have been received in the post-marketing period, therefore with current knowledge, a possible risk for the development of lymphomas, leukaemia or other haematopoietic or solid malignancies in patients treated with a TNF-antagonist cannot be excluded. Malignancies, some fatal, have been reported among children, adolescents and young adults (up to 22 years of age) treated with TNF-antagonists (initiation of therapy ≤ 18 years of age) in the post marketing setting. Melanoma and non-melanoma skin cancer (NMSC) have been reported in patients treated with TNF-antagonists, including Enbrel. Post-marketing cases of Merkel cell carcinoma have been reported very infrequently in patients treated with Enbrel. Periodic skin examination is recommended for all patients, particularly those with

risk factors for skin cancer. Enbrel has not been studied in combination with other systemic therapies or phototherapy for the treatment of psoriasis. Monitor closely if patient develops new infection during treatment. Discontinue treatment if serious infection or allergic reaction develops or if blood dyscrasias are confirmed. Caution should be used in patients who have moderate to severe alcoholic hepatitis and Enbrel should not be used in patients for the treatment of alcoholic hepatitis. Discontinue temporarily if significantly exposed to varicella virus. Live vaccines should not be given concurrently with Enbrel. Paediatric patients should have received all vaccines recommended in current immunization guidelines prior to starting Enbrel. Treatment with Enbrel may result in the formation of autoantibodies. Enbrel is not recommended for use in patients with Wegener's granulomatosis. There have been reports of hypoglycaemia in Enbrel patients receiving medication for diabetes, necessitating a reduction in anti-diabetic medication in some of these patients. There have been reports of Inflammatory Bowel Disease (IBD) and uveitis in JIA patients being treated with Enbrel. Caution should be exercised when treating the elderly and with particular attention to occurrence of infections. **Pregnancy & Lactation:** Enbrel is not recommended in pregnant or breast-feeding women. **Undesirable Effects:** Adults: The most commonly reported adverse reactions are injection site reactions, infections, allergic reactions, development of autoantibodies, itching, and fever. See SmPC for less commonly reported side effects. TNF-antagonists, such as Enbrel, affect the immune system and their use may affect the body's defences against infection and cancer. Serious infections affect fewer than 1 in 100 patients treated with Enbrel. Reports have included fatal and life-threatening infections and sepsis. Various malignancies have also been reported with use of Enbrel, including cancers of the breast, lung, skin and lymphatic system (lymphoma). Serious infections and other adverse events such as uncommon reports of: thrombocytopenia, systemic vasculitis, uveitis and scleritis, interstitial lung disease, rare reports of tuberculosis, opportunistic infections, anaemia, leucopenia, neutropenia, pancytopenia, seizures, worsening of heart failure, autoimmune hepatitis, Steven Johnson's syndrome and very rare reports of: anaphylaxis, toxic epidermal necrolysis and aplastic anaemia have been reported. Reactivation of hepatitis B (a liver infection) and worsening of symptoms of dermatomyositis have also been reported. Central and peripheral demyelinating events have been seen rarely and very rarely, respectively, with Enbrel use. There have been rare reports of lupus, lupus-related conditions, and vasculitis. Rate of new malignancies was similar to that expected for the population studied. Fatalities associated with serious infections, pancytopenia, aplastic anaemia and interstitial lung disease have also been reported. **Paediatrics:** Generally as for adults, except the following were more common: headaches, nausea, vomiting and abdominal pain. In addition the following were reported as severe events: varicella, appendicitis, gastroenteritis, depression/ personality disorder, cutaneous ulcer, oesophagitis/gastritis, group A streptococcal septic shock, type 1 diabetes mellitus and soft tissue and post operative wound infection. There have been post-marketing reports of IBD and uveitis in JIA patients, including cases indicating a positive re-challenge. See section 4.8 of the SmPC for how to report adverse reactions. **Package Quantities:** Enbrel Pre-filled Syringe: Each carton contains 4 pre-filled syringes containing either 25 mg or 50 mg of Enbrel and 4 alcohol swabs. Enbrel Pre-filled Pen (MYLUC): Each carton contains 4 pre-filled pens containing 50 mg of Enbrel and 4 alcohol swabs. Enbrel Powder: Each carton contains 4 vials of Enbrel 25 mg powder, 4 pre-filled syringes of water for injections, 4 needles, 4 vial adaptors and 8 alcohol swabs. Enbrel Paediatric (10 mg): Each carton contains 4 vials of Enbrel 10 mg powder, 4 pre-filled syringes of water for injections, 4 needles, 4 vial adaptors and 8 alcohol swabs. **European Marketing Authorisation Numbers:** Enbrel Pre-filled Syringe 25 mg: EU/1/99/126/013 Enbrel Pre-filled Syringe 50 mg: EU/1/99/126/017 Enbrel Pre-filled Pen (MYLUC) 50 mg: EU/1/99/126/020 Enbrel Powder 25 mg: EU/1/99/126/003 Enbrel Paediatric 10 mg: EU/1/99/126/022. **Legal Category:** S1A. **European Marketing Authorisation Holder:** Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK. **For full prescribing information see the Summary of Product Characteristics. For further information on this medicine please contact:** Pfizer Medical Information on 1800 633 363 or at EUMEDINFO@pfizer.com. For queries regarding product availability please contact: Pfizer Healthcare Ireland, Pfizer Building 9, Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24 + 353 1 4676500. **API Reference Number:** EN\_8\_0. **Pfizer number:** 2013-0003980. **Date of Prescribing Information:** July 2014

## References:

1. Enbrel (etanercept) SmPC. [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/EPAR\\_-\\_Product\\_Information/human/000262/WC500027361.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000262/WC500027361.pdf). Last accessed June 2014.
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book chapters, including being a co-author on two Cochrane systematic reviews.

I am the inaugural Director of the Research Centre for Psychological Health based in the School of Psychology. The centre addresses important social issues by focussing research on applications of psychological science to enhance mental health and well-being.

I contribute significantly to the discipline of psychology at both a national and international level. I am on the Advisory Committee for the European Federation of Psychologists' Associations' (EFPA) Congress on Psychology for Health, which formulates recommendations for European healthcare policies.

### Una Martin CNS

As a nurse I have always been passionate about caring for patients with rheumatology conditions and I admire their courage and determination, living with the uncertainty that inflammatory arthritis can bring to them as an individual.

I completed general training in London, I have worked in Rheumatology since 1994.

I was appointed as the first CNS in Rheumatology in the North West London NHS trust in 1999. I returned to Ireland in 2004 and joined the rheumatology team at University Hospital Waterford in 2005. In 2007 I was appointed CNS in rheumatology. I completed the Graduate Diploma in Rheumatology in University College Dublin in 2007 graduating with a distinction. In 2010 I completed a masters in clinical practice at University College Dublin. I am a registered prescriber of ionising radiation and recently completed the nurse prescribing course at RCSI.

I am responsible for the running of the rheumatology service which is an outpatient and day care facility supported by myself and 2 staff nurses.

When not immersed in the world of rheumatology I like to garden and cook, in particular Italian feasts for family and friends.



### Susan Murphy

University Hospital Waterford

Susan Murphy is a Chartered Physiotherapist and member of the Irish Society of Chartered Physiotherapists (ISCP). She holds a BSc Physiotherapy from University College Dublin (UCD), an MSc (Manual Therapy) from Coventry University, England and a PhD from UCD.

Clinically Susan has worked in a variety of settings, St. Mary's Hospital, Paddington, London, St. Vincent's University Hospital, Dublin, The Blackrock Clinic, Dublin and currently is Clinical Specialist Physiotherapist at the Spinal Triage Clinic, University Hospital Waterford. Her particular expertise is in the physiotherapy management of benign musculoskeletal dysfunction. In addition to her clinical work, Susan lectures on a part time basis at the School of Physiotherapy, UCD.

Susan's main research interest is the management of low back pain (LBP). Her PhD explored the effectiveness of physiotherapy led group exercise/education interventions for patients with LBP. She has presented her research findings both nationally and internationally and has several publications.



### Fidelma Farley

Oscailt Centre, Ranelagh, Dublin 6

Fidelma Farley is a Breathworks Mindfulness Trainer

([www.breathworks-mindfulness.co.uk](http://www.breathworks-mindfulness.co.uk)).

She teaches mindfulness and compassion for the management of chronic pain and long-term health conditions, and runs courses and workshops for the M.S. Society, the M.E. Trust, the Irish Heart Foundation, for the general public and for healthcare professionals. She also teaches mindfulness and compassion for stress and general well-being.



### Dr Connail McCrory

St. James Hospital, Dublin

Graduated RCSI 1988. Trained in Ireland, UK and Karolinska Institute, Stockholm and Lund University Hospital, Sweden.

Dean Faculty of Pain Medicine 2015-18

Medical Director Pain Medicine, St. James Hospital.

Senior Lecturer, School of Medicine, Trinity College Dublin

Primary Investigator, Trinity College Institute of Neuroscience, Trinity College Dublin

Research Interests: Spinal neuronal inflammatory responses in man leading to pain perception. Effect of Spinal Cord Stimulation on Cerebrospinal Fluid cytokines in vivo in man. Investigation of Spinal Neuronal Mechanism of Chronic Pain in man by CSF analysis. Analgesic Agent Pharmacokinetics in Human Cerebrospinal Fluid and investigation of their effect on CSF cytokines.



### Dr Siobhan MacHale

Beaumont Hospital, Dublin 9

Dr Siobhan MacHale qualified from UCD and trained as a physician in Ireland, before progressing to train in psychiatry in Edinburgh in 1991. She has practised as a Consultant Liaison Psychiatrist for 16 years, initially in the Royal Infirmary of Edinburgh, before returning to her current post in Beaumont Hospital in 2006. She is a Fellow of the Royal College of Psychiatrists, as well as a Fellow of the Royal College of Physicians of Ireland and the Royal College of Physicians of Edinburgh. As a Liaison Psychiatrist, her primary role is in the care and management of the mental health needs of patients in the general hospital setting, incorporating the art and language of mind-body medicine. Central to this is the care of patients presenting with disabling pain as a core feature of their health journey.

Dr Siobhán MacHale MPhil FRCPi FRCP (Edin) FRCPsych Consultant Liaison Psychiatrist Dept of Psychiatry, Beaumont Hospital, Dublin 9 & Senior Lecturer RCSI Ireland





# CLARITY IN THE TREATMENT PLAN - RIGHT FROM THE START



For patients with Rheumatoid Arthritis, Psoriatic Arthritis or Axial Spondyloarthritis

**RA**  
RHEUMATOID ARTHRITIS®

◦ **Rheumatoid arthritis:** Cimzia®, in combination with methotrexate (MTX), is indicated for the treatment of moderate to severe, active rheumatoid arthritis (RA) in adult patients when the response to disease-modifying antirheumatic drugs (DMARDs) including methotrexate, has been inadequate.

**PsA**  
PSORIATIC ARTHRITIS®

◦ **Psoriatic arthritis:** Cimzia®, in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adults when the response to previous DMARD therapy has been inadequate.

**axSpA**  
AXIAL SPONDYLOARTHRITIS®

◦ **Axial spondyloarthritis:** Cimzia® is indicated for the treatment of adult patients with severe active axial spondyloarthritis.

## PRESCRIBING INFORMATION

(Please consult the Summary of Product Characteristics (SPC) before prescribing.)  
**Cimzia®**

**Certolizumab Pegol**

**Active Ingredient:** Pre-filled syringe contains 200 mg certolizumab pegol in one ml.

**Indication(s):** **Rheumatoid arthritis (RA):** Cimzia, in combination with methotrexate (MTX), is indicated for the treatment of moderate to severe, active RA in adult patients when the response to disease-modifying antirheumatic drugs (DMARDs) including MTX, has been inadequate. Cimzia can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate. Cimzia has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with MTX.

**Axial spondyloarthritis:** Cimzia is indicated for the treatment of adult patients with severe active axial spondyloarthritis, comprising:

**Ankylosing spondylitis (AS):** Adults with severe active ankylosing spondylitis who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs).

**Axial spondyloarthritis without radiographic evidence of AS:** Adults with severe active axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to NSAIDs.

**Psoriatic arthritis:** Cimzia in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adults when the response to previous DMARD therapy has been inadequate. Cimzia can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate.

**Dosage and Administration:** Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of conditions for which Cimzia is indicated in adult patients. Patients should be given the special alert card. For RA and psoriatic arthritis MTX should be continued during treatment with Cimzia where appropriate.

**Loading dose:** The recommended starting dose is 400 mg (given as 2 subcutaneous injections of 200 mg each) at weeks 0, 2 and 4.

**Maintenance dose:** **RA and Psoriatic Arthritis:** The recommended maintenance dose is 200 mg every 2 weeks. Once clinical response is confirmed, an alternative maintenance dose of 400 mg every 4 weeks can be considered. **Axial spondyloarthritis:** The recommended maintenance dose is 200 mg every 2 weeks or 400 mg every 4 weeks. For the above indications continued therapy should be carefully reconsidered in patients who show no evidence of therapeutic benefit within the first 12 weeks of treatment.

**Missed dose:** Advise patients to inject the next dose as soon as they remember and inject

subsequent doses as originally instructed.

**Paediatric population (<18 years old):** Not recommended. Consult SPC for further information.

**Contraindications:** Hypersensitivity to the active substance or to any of the excipients; active tuberculosis or other severe infections such as sepsis or opportunistic infections; moderate to severe heart failure (NYHA classes III/IV).

**Precautions:** Prior to treatment with Cimzia all patients to be appropriately screened for tuberculosis, e.g. tuberculin skin test and chest X-ray (local recommendations may apply) and results recorded on the patient alert card. False negative tuberculin skin test results are possible in severely ill or immunocompromised patients. Do not initiate treatment in cases of latent tuberculosis, clinically important active infection, including chronic or localised infections until the infection is controlled. In patients with a past history of latent tuberculosis use of anti-tuberculosis therapy must be started before initiation of Cimzia. Evaluate and monitor patients closely for signs and symptoms of infections including chronic and local infections and active and latent tuberculosis. Treatment must not be initiated until infection is controlled. Some patients who have been successfully treated for active tuberculosis have redeveloped tuberculosis while being treated with Cimzia. Monitor patients closely for signs of infection during and up to 5 months after treatment in order to minimise delay in diagnosis and treatment. Serious infections (including sepsis, tuberculosis, miliary tuberculosis, disseminated and extrapulmonary disease) and opportunistic infections (including histoplasmosis, nocardia, candidiasis) have been reported with some fatal outcomes. Caution is advised in patients with a history of recurring or opportunistic infections including those on concomitant corticosteroid or immunosuppressive medications or elderly. Patients should be tested for HBV infection before initiating treatment with Cimzia and if treated should be continually monitored. In patients receiving TNF antagonists, HBV reactivation has occurred in chronic carriers with some fatal outcomes. Cimzia should be discontinued and effective antiviral therapy and appropriate supportive treatments initiated. There is an increase in background risk for lymphoma and leukaemia in patients with long-standing highly active RA. Periodic skin examination is recommended particularly for patients with risk factors for skin cancer. Exercise caution when initiating TNF antagonist therapy in patients with a history of malignancies and when considering continuing treatment if patients develop lymphoma, leukaemia, mild congestive heart failure and demyelinating disorders such as multiple sclerosis. Advise patients to seek immediate medical attention if they develop signs and symptoms suggestive of tuberculosis, blood dyscrasias or infection. Discontinue treatment if patients develop significant haematological abnormalities including aplastic anaemia, leukopenia, pancytopenia, thrombocytopenia; lupus-like syndrome; mild congestive heart failure and demyelinating disorders such as multiple sclerosis. There is a potential risk of worsening of congestive heart failure with TNF antagonists including Cimzia. As for all TNF antagonists COPD and heavy smoking may put patients at greater risk of malignancies.

Patients receiving Cimzia may receive vaccination except live vaccines. Live vaccines should not be administered concurrently with Cimzia. The 14 day half-life of certolizumab pegol should be taken into account prior to planned surgical procedures. Cimzia may cause erroneously elevated (aPTT) assay results in patients without coagulation abnormalities.

**Interactions:** The combination of Cimzia and anakinra or abatacept is not recommended.

**Pregnancy and lactation:** Cimzia is not recommended in pregnancy or breastfeeding. Women of childbearing potential should use adequate contraception up to 5 months after the last administered dose.

**Driving etc.:** Cimzia may have a minor influence on the ability to drive and use machines. Dizziness may occur following administration. Caution is advised.

**Adverse Effects:** Common adverse-effects (+1/100 to <1/10): Bacterial infections (including abscess) and viral infections (including herpes zoster, papillomavirus and influenza), eosinophilic disorders, leukopenia (including neutropenia, lymphopenia), headaches (including migraine), sensory abnormalities, hypertension, nausea, hepatitis (including hepatic enzyme increased), rash, pyrexia, pain (any site), asthenia, pruritus (any site), injection site reactions. **Consult SPC in relation to other side effects.** Pharmaceutical Precautions: Store in refrigerator (2°-8°C). Do not freeze. Keep the pre-filled syringe in the outer carton in order to protect from light.

**Legal Category:** POM

**Marketing Authorisation Number(s):** EU/1/09/544/001

**UK NHS Cost :** £357.50 per syringe (200 mg)

**Marketing Authorisation Holder:**

UCB Pharma S.A., Allée de la Recherche 60, 1070 Brussels, Belgium.

**Further information is available from:**

UCB Pharma Ltd, 208 Bath Road, Slough, Berkshire, SL13WE.

Tel: +44 (0)1753 534655. Fax: +44 (0)1753 536632.

UCB (Pharma) Ireland Ltd, United Drug House, Magna Drive,

Magna Business Park, City West Road, Dublin 24, Ireland

Tel: +353 14637395 Fax: +353 14637396

Email: medicalinformationuk@ucb.com

**Date of Revision:** 11/2014 (UK/14C10101).

Cimzia is a registered trademark.

**UK Specific Information**

Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)  
Adverse events should also be reported to UCB Pharma Ltd.





## ISR Board members

### Professor David Kane

Prof David Kane attended medical school at Trinity College, Dublin, Ireland and was conferred MB BCH BAO BA in 1991, PhD in 2002 and FRCPI in 2006. He has trained in rheumatology with Prof. Barry Bresnihan and Prof. Oliver FitzGerald at St. Vincent's University Hospital, Dublin, Ireland and with Prof Roger Sturrock, Prof Iain McInnes and Dr Peter Balint at Glasgow Royal Infirmary, Glasgow, United Kingdom. He was appointed as Senior Lecturer in Rheumatology at the University of Newcastle (2003-2005) and is currently working as Consultant Rheumatologist at the Adelaide and Meath Hospital and Clinical Professor in Rheumatology at Trinity College Dublin. His special interests are musculoskeletal ultrasound, spondyloarthopathy and synovial inflammation. He is a member of the European Working Party on Musculoskeletal Ultrasound and the OMERACT special interest group on musculoskeletal ultrasound, previous organiser of the BSR Musculoskeletal Ultrasound course and is Faculty member of the EULAR Musculoskeletal ultrasound course. He has served as a Board member of the Irish Osteoporosis Society, as Treasurer of the Irish Society for Rheumatology and is currently a Board member of Arthritis Ireland.



### Dr Frances Stafford

Frances is a graduate of UCD, spent almost a decade in North America, training in Rheumatology first at University of Toronto, followed by a fellowship at Massachusetts General Hospital & Harvard Medical School. She was awarded a 4 year Arthritis Foundation Postdoctoral Fellowship, which I completed at the NIH, and then went on staff at the NIH. Frances is American Board Certified in Internal Medicine and in Rheumatology. She has been Consultant at Blackrock Clinic since 1995.



### Dr Sinéad Harney

Dr Sinéad Harney graduated from UCG in 1994 and did her specialist training in Rheumatology and General Medicine in Dublin. She completed her training in Oxford in 2005 and was awarded a DPhil by thesis titled "Major Histocompatibility Genetics of Rheumatoid Arthritis". She was appointed to a Consultant Rheumatologist post in Cork University Hospital in 2005 and has worked there since. She completed a Masters in Sports and Exercise Medicine in UCC in 2007. Her research interests include – Genetics of inflammatory arthritis and occult cardiovascular disease in Rheumatoid Arthritis and she has over 90 publications. She is currently the treasurer of the Irish Society of Rheumatology and a board member of the TUE committee of the Irish Sports Council.



### Dr Suzanne Donnelly

Dr Suzanne Donnelly graduated from Trinity College Dublin, trained in Ireland and England and was appointed consultant rheumatologist at St. George's Hospital and Medical School, London in 2002. She returned to Ireland in 2005 to work part time as Consultant Rheumatologist in the Mater Misericordiae University Hospital. Her clinical and educational research interests include systemic autoimmune disease, Systemic Lupus Erythematosus and Care in Medicine. Suzanne has held academic posts in medical education since 1996 including in Trinity College Dublin; the University of Oxford and in London, and joined UCD as Director of Clinical Education in 2008, to lead the development of early clinical education. She was responsible for a series of innovative educational strategies across all disciplines including the development of a patient educator programme in association with Arthritis Ireland. She led the first national undergraduate curriculum project in Ireland, published as the ISR Undergraduate Curriculum in Rheumatology in 2009, and is a contributing author to the textbooks *Medicine at A Glance* & *The Rheumatology Handbook*. She was ISR nominee to the board of Arthritis Ireland (2008-13), a board member of Raynauds and Scleroderma Ireland (2007-10) and is a medical patron of Lupus Group Ireland.



### Dr Sandy Fraser

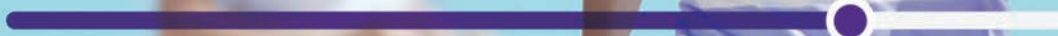
Consultant Rheumatologist, General Physician and Honorary Senior Lecturer, University Hospitals Limerick. Dr. Alexander Fraser graduated in medicine from Trinity College Dublin in 1991. He began practicing Rheumatology in 1996 and the following year was appointed Specialist Registrar in Rheumatology at the Yorkshire Deanery. Training with Professor Emery's group in Leeds he developed a research interest in clinical, immunological and therapeutic aspects of Rheumatoid Arthritis, Psoriatic Arthritis and the Sero-negative Spondyloarthropathies. He was appointed Consultant Rheumatologist and Honorary Senior Lecturer at the Leeds Teaching Hospitals NHS Trust, working at The Leeds General Infirmary and St. James' University Hospital in October 2001, and working closely with Professor Emery and Professor Doug Veale he published in the area of Angiogenesis, Vascularity and Inflammation in early and established arthritis and Biomarkers of cartilage turnover. Dr Fraser took up his current appointment as Consultant Rheumatologist, General Physician and Honorary Senior Lecturer at the University Hospitals Limerick in 2006. In conjunction with the University of Limerick Graduate Entry Medical School (GEMS) Dr. Fraser and his team have continued their strong academic interests while managing a busy clinical practice.





12 weeks of psoriatic arthritis control for

# Play without pause



After 2 starter doses, 1 dose of Stelara® every 12 weeks can reliably control the signs and symptoms of psoriatic arthritis.<sup>1</sup>



#### STELARA® solution for injection in pre-filled syringe

**PRESCRIBING INFORMATION. ACTIVE INGREDIENT(S):** Ustekinumab

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

**INDICATION(S):** **Plaque psoriasis:** Treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate or PUVA. **Psoriatic arthritis:** Alone or in combination with methotrexate for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. **DOSAGE & ADMINISTRATION:** Under the guidance and supervision of a physician experienced in diagnosis and treatment of psoriasis or psoriatic arthritis. Subcutaneous injection. Avoid areas with psoriasis. For self-injecting patients ensure appropriate training, follow-up and monitoring during treatment. **Plaque psoriasis, adults & elderly:** Patients ≤ 100kg, 45 mg at week 0 followed by a 45 mg dose at week 4, then every 12 weeks. Patients >100 kg, 90 mg at week 0 followed by a 90 mg dose at week 4, then every 12 weeks (45 mg was less effective in these patients). **Psoriatic arthritis, adults & elderly:** 45 mg at week 0 followed by a 45 mg dose at week 4, then every 12 weeks. Alternatively, 90 mg may be used in patients with a body weight >100 kg. Consider discontinuation if no response after 28 weeks. **Children <18 years:** Not recommended. **Renal & Hepatic impairment:** Not studied. **CONTRAINDICATIONS:** Hypersensitivity to product; clinically important, active infection. **SPECIAL WARNINGS & PRECAUTIONS: Infections:** Potential to increase risk of infections and reactivate latent infections. Caution in patients with a chronic infection or history of recurrent infection, particularly TB. Patients should be evaluated for tuberculosis prior to initiation of STELARA. Consider anti-tuberculosis therapy prior to initiation of STELARA in patients with past history of latent or active tuberculosis. Patients should seek medical advice if signs or symptoms suggestive of an infection occur. If a serious

infection develops, they should be closely monitored and STELARA should not be administered until infection resolves. **Malignancies:** Potential to increase the risk of malignancy. No studies in patients with a history of malignancy or in patients who develop malignancy while receiving STELARA. Monitor all patients, in particular those older than 60, patients with a medical history of prolonged immunosuppressant therapy or those with a history of PUVA treatment for non-melanoma skin cancer. **Concomitant immunosuppressive therapy:** Caution, including when changing immunosuppressive biologic agents. **Hypersensitivity reactions:** Serious hypersensitivity reactions (anaphylaxis and angioedema) reported, in some cases several days after treatment. If these occur appropriate therapy should be instituted and, STELARA discontinued immediately. **Latex sensitivity:** Needle cover contains natural rubber (latex), may cause allergic reactions. **Immunotherapy:** Not known whether STELARA affects allergy immunotherapy. **Serious skin conditions:** Exfoliative dermatitis has been reported following treatment. Discontinue STELARA if a drug reaction is suspected. **SIDE EFFECTS: Common:** dental infections, upper respiratory tract infection, nasopharyngitis, dizziness, headache, oropharyngeal pain, diarrhoea, nausea, pruritus, back pain, myalgia, arthralgia, fatigue, injection site erythema, injection site pain, antibodies to ustekinumab. **Other side effects include:** cellulitis, serious hypersensitivity reactions (including anaphylaxis, angioedema), skin exfoliation, exfoliative dermatitis. **Refer to SmPC for other side effects. FERTILITY:** The effect of ustekinumab has not been evaluated. **PREGNANCY:** Should be avoided. Women of childbearing potential: Use effective contraception during treatment and for at least 15 weeks post-treatment. **LACTATION:** Limited data in humans. **INTERACTIONS:** *In vitro*, STELARA had no effect on CYP450 activities. **Vaccinations:** Live vaccines should not be given concurrently with STELARA, and should be withheld for at least 15 weeks after last dose of STELARA. STELARA can resume at least 2 weeks after such vaccinations. No data on

secondary transmission of infection by live vaccines in patients receiving STELARA. **Concomitant immunosuppressive therapy:** Psoriasis: The safety and efficacy of STELARA in combination with other immunosuppressants, including biologics, or phototherapy have not been evaluated. **Refer to SmPC for full details of interactions. LEGAL CATEGORY:** Prescription Only Medicine. **PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBER:** 45mg; 1 x 0.5ml pre-filled syringe. EU/1/08/494/003. 90mg; 1 x 1.0ml pre-filled syringe. EU/1/08/494/004. **MARKETING AUTHORISATION HOLDER:** JANSSEN-CILAG INTERNATIONAL NV, Turnhoutseweg 30, B-2340 Beerse, Belgium. **FURTHER INFORMATION IS AVAILABLE FROM:** Janssen-Cilag Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG UK. © Janssen-Cilag Ltd 2014. Prescribing information last revised: 11/2014

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. **Healthcare professionals are asked to report any suspected adverse events via:** –HPRA Pharmacovigilance, Eurlorf Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, E-mail: medsafety@hpra.ie

Adverse events should also be reported to Janssen-Cilag Ltd on +44 1494 567447.

References: 1. Stelara SmPC available from [www.medicines.ie](http://www.medicines.ie)

Date of preparation: February 2015  
PHIR/STE/0913/0002a(1)a







### Dr Donough Howard

Donough Howard is a Consultant Rheumatologist at St James's Hospital and Hermitage Medical Clinic. Dr Howard is the national specialty director for rheumatology. He graduated from RCSI and completed postgraduate training both in Ireland and the US. He previously worked in Lahey Clinic Medical Centre, with academic appointments to both Harvard and Tufts Medical Schools. Dr Howard has published in the fields of vasculitis and also has subspecialty interests in the fields of scleroderma.



### Dr Gary Wright

Dr Wright qualified from Queens University in 1987 and was appointed Consultant Rheumatologist at the Royal Victoria Hospital and Musgrave Park Hospitals in Belfast in 1998. He is an Honorary Clinical lecturer at Queen's University Belfast. He trained in Rheumatology in Belfast and spent a further year as Honorary Senior Registrar in Nottingham with Professor Mike Doherty.

His Research interests include the genetics of osteoarthritis and crystal disease, early diagnosis and treatment of inflammatory arthritis and musculoskeletal ultrasound in rheumatic disorders.



### Dr Orla Killeen

Dr Orla Killeen qualified from UCG (NUI) Galway in 1996. She trained in General Paediatrics in Our Lady's Hospital for Sick Children, Crumlin and in Temple Street University Hospital, Dublin before sub-specialising in Paediatric Rheumatology. She undertook her paediatric rheumatology training at Great Ormond Street Children's Hospital, London and went on to complete a Barbara Ansell Fellowship in Paediatric Rheumatology in the Royal Hospital for Sick Children, Glasgow. She was appointed as Ireland's first Paediatric Rheumatologist in 2004, and is based at Our Lady's Children's Hospital, Crumlin and St Vincent's University Hospital, Dublin since July 2006. She is the Clinical lead for the National Centre for Paediatric Rheumatology (NCPR), providing care for patients both on a local and national level up to 18 years of age. Her areas of interest include Adolescent Rheumatology Transition Care as well as JIA, Down's arthropathy and Auto-Inflammatory syndromes.



### Eamonn Molloy

Eamonn Molloy graduated from University College Dublin (1997) and completed rheumatology and internal medicine training in Ireland. He obtained an MD at RCSI (2006), which focused on calcium crystal induced inflammation. From 2005, he underwent subspecialty fellowship training in vasculitis at the Cleveland Clinic, completed a MS (Clinical Research) at Case Western Reserve University and then joined the staff at the Vasculitis Center and RJ Fasnemeyer Center for Clinical Immunology at the Cleveland Clinic. In 2010, he was appointed as a consultant rheumatologist at St Vincent's University Hospital and is a UCD Senior Clinical Lecturer. He is the author of approximately 50 publications largely pertaining to vasculitis, complications of biologic therapy and crystal induced arthritis. Currently, his primary research focus is giant cell arteritis.



### Dr John Stack (SPR Rep)

John Stack is this years SpR representative on the ISR committee. He is a 4th year rheumatology SpR currently based at Connolly Hospital Blanchardstown and has previously worked at St James Hospital, Midlands Regional Hospital Mullingar and Cork University Hospital. He is a graduate of University College Cork.



### Dr Clare Matthews and Adrian Pendleton are members of the ISR Board

## SpR Training Update

There are currently 23 SpRs enrolled on the rheumatology specialist training scheme in Ireland. Whilst the majority are employed in clinical and research posts in Ireland, many are pursuing clinical and research fellowships abroad in centers across the UK and Northern America. On behalf of the SpRs I would like to thank Dr Donough Howard for his ongoing time and commitment as specialty director. I would also like to acknowledge the pharmaceutical industry in their support of SpRs attending international meetings and pursuing fellowships abroad which provide invaluable learning and research opportunities. We hope we can look forward to their continued support in the future.





## The first biologic approved in both SC and IV formulations for the treatment of moderate to severe active rheumatoid arthritis\*

Patient-reported improvements in pain, physical function, work productivity and fatigue were maintained after 2 years<sup>1</sup>



**ORENCIA®**  
(abatacept)



**Bristol-Myers Squibb**

\* In combination with methotrexate

**ORENCIA® (abatacept) PRESCRIBING INFORMATION.** See Summary of Product Characteristics before prescribing. **PRESENTATION:** 250 mg powder for concentrate for solution for IV infusion containing 250 mg abatacept per vial. Each ml contains 25 mg of abatacept, after reconstitution; 125 mg pre-filled syringe for SC injection. Each pre-filled syringe contains 125 mg of abatacept in 1 ml. **INDICATION:** *Rheumatoid arthritis (IV infusion and SC pre-filled syringe):* Treatment of moderate to severe active rheumatoid arthritis (RA), in combination with methotrexate, in adult patients who have responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate (MTX) or a Tumour Necrosis Factor (TNF)-alpha inhibitor. A reduction in the progression of joint damage and improvement of physical function have been demonstrated during combination treatment with abatacept and methotrexate. See SmPC. *Polyarticular Juvenile Idiopathic Arthritis (pJIA) (IV infusion only):* Orenzia 250 mg powder for concentrate for solution for IV infusion is indicated for treatment of moderate to severe active pJIA in paediatric patients 6 years of age and older who have had an insufficient response to other DMARDs including at least one TNF inhibitor. **DOSAGE and ADMINISTRATION:** Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA. Orenzia 250 mg powder for concentrate for solution for IV infusion. *Adults and elderly:* Patients weighing < 60 kg: 500 mg (2 vials). Patients weighing ≥ 60 kg to ≤ 100 kg: 750 mg (3 vials). Patients weighing > 100 kg: 1000 mg (4 vials). *Treatment of pJIA:* Paediatric patients, 6 to 17 years of age, weighing less than 75 kg: 10 mg/kg. Paediatric patients weighing 75 kg or more: to be administered adult dosage, not exceeding a maximum dose of 1,000 mg. See SmPC for details of reconstitution and administration as a 30 minute IV infusion. After initial administration, Orenzia should be given at 2 and 4 weeks, then every 4 weeks thereafter. *Children:* Use in children below 6 years of age is not recommended. Orenzia 125 mg solution for injection (SC pre-filled syringe) *Adults and elderly:* Orenzia SC may be initiated with or without an intravenous (IV) loading dose. Orenzia SC should be administered weekly at a dose of 125 mg by subcutaneous injection regardless of weight. If a single IV infusion is given to initiate treatment (IV loading dose before SC administration), the first 125 mg abatacept SC should be administered within a day of the IV infusion, followed by the weekly 125 mg abatacept SC injections. Patients transitioning from Orenzia IV therapy to SC administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose. *Children:* Administration in children below 18 years of age is not recommended. The continuation of treatment with abatacept should be re-assessed if patients do not respond within 6 months. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or excipients. Severe and uncontrolled infections such as sepsis and opportunistic infections. **WARNINGS AND PRECAUTIONS:** *Allergic Reactions:* Caution in patients with a history of allergic reactions. Anaphylaxis or anaphylactoid reactions can occur after the first infusion and can be life threatening. Orenzia IV or SC should be discontinued permanently if a patient develops serious allergic or anaphylactic reaction. *Infections:* Caution should be exercised when considering the use in patients with a history of frequent infections, or underlying conditions which may predispose to infection. Treatment with Orenzia should not be initiated with patients with active infections until infections are controlled. Screening for tuberculosis and hepatitis B should be performed prior to therapy. Any patient who develops a new infection should be closely monitored and Orenzia should be discontinued if a patient develops a serious infection. Monitor patients for signs of infection when transitioning from TNF-antagonist to Orenzia. Co-administration of Orenzia with biologic immunosuppressive or immunomodulatory agents could potentiate the effects of abatacept on the immune system. Treatment with immunosuppressive therapy may be associated with progressive multifocal leukoencephalopathy (PML). Orenzia treatment should be discontinued if neurological symptoms suggestive of PML occur, and appropriate diagnostic measures initiated. *Malignancies:* The potential role of Orenzia in the development of malignancies is unknown, see SmPC. *Elderly:* Caution should be used when treating elderly patients due to a higher incidence of infections and malignancies in this patient group. *Autoimmune processes:* Theoretical risk of deterioration in autoimmune disease. *Immunisation:* Live vaccines should not be given simultaneously or within 3 months of discontinuation of Orenzia. See SmPC. **DRUG INTERACTIONS:** Concomitant therapy of Orenzia with a TNF-inhibitor is not recommended. No major safety issues were identified with the use of Orenzia in combination with sulfasalazine, hydroxychloroquin or leflunomide. **PREGNANCY AND LACTATION:** Do not use in pregnancy unless clearly necessary. Women should use contraception and not breast-feed during treatment and for up to 14 weeks after last dose treatment. **UNDESIRABLE EFFECTS:** In adult placebo-controlled trials the following adverse drug reactions were reported. *Very Common (≥ 1/10):* upper respiratory tract infection including tracheitis, nasopharyngitis. *Common (≥ 1/100 to < 1/10):* Lower respiratory tract infection (including bronchitis), urinary tract infection, herpes infections (including herpes simplex, oral herpes and herpes zoster), rhinitis, pneumonia, influenza, leukopenia, headache, dizziness, paraesthesia, conjunctivitis, hypertension, flushing, blood pressure increased, cough, abdominal pain, diarrhoea, nausea, dyspepsia, mouth ulceration, aphthous stomatitis, vomiting, liver function test abnormal (including transaminases increased), rash (including dermatitis), alopecia, pruritus, pain in extremity, fatigue, asthenia, local injection site reactions\*, systemic injection reactions\* (e.g. pruritus, throat tightness, dyspnea) (\*Orenzia SC). *Uncommon (≥ 1/1,000 to < 1/100):* Tooth infection, onychomycosis, sepsis, musculoskeletal infections, skin abscess, pyelonephritis, pelvic inflammatory disease, basal cell and squamous cell carcinoma, skin papilloma, thrombocytopenia, hypersensitivity, depression, anxiety, sleep disorder (including insomnia), migraine, dry eye, visual acuity reduced, vertigo, palpitations, tachycardia, bradycardia, hypotension, hot flush, vasculitis, blood pressure decreased, bronchospasm, wheezing, dyspnea, gastritis, increased tendency to bruise, dry skin, urticaria, psoriasis, erythema, hyperhidrosis, arthralgia, amenorrhoea, menorrhagia, influenza like illness, weight increased. *Rare (≥ 1/10,000 to < 1/1,000):* Tuberculosis, bacteraemia, gastrointestinal infection, lymphoma, lung neoplasm malignant, throat tightness. See SmPC for further details. **LEGAL CATEGORY:** POM. **MARKETING AUTHORISATION NUMBER:** Orenzia 250 mg concentrate for solution for infusion - EU/1/07/389/001, 1 vial pack; Orenzia 125 mg solution for injection - EU/1/07/389/008, 4 pre-filled syringes with needle guard. **MARKETING AUTHORISATION HOLDER:** Bristol-Myers Squibb Pharma EEIG, Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 3DH, UK. **FURTHER INFORMATION FROM:** Bristol-Myers Squibb Pharmaceuticals, Watery Lane, Swords, Co. Dublin. Tel: 1-800-749-749 or medicalinformation@bms.com. **DATE OF PREPARATION:** September 2014. Job No: 427IE14PR06813-01

Reporting of suspect adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Freepost, HPRA Pharmacovigilance, Earlsfort Terrace, IRL, Dublin 2. Tel: +353 1 6764971; Fax: +353 1 676 25 17. Website: [www.hpra.ie](http://www.hpra.ie), [medsafety@hpra.ie](mailto:medsafety@hpra.ie). Adverse reactions should also be reported to Bristol-Myers Squibb Medical Information on 1 800 749 749 or [medical.information@bms.com](mailto:medical.information@bms.com).





## ISR Presidents

**Prof D. Kane** 2014 – present  
Dublin

**Dr G. Wright** 2012 – 2014  
Belfast

**Dr R. Kavanagh** 2008 - 2010  
Galway

**Dr J. Lee** 2006 - 2008  
Craigavon

**Dr P. O'Connell** 2004 - 2006  
Dublin

**Prof O. FitzGerald** 2004 - 2002  
Dublin

**Dr A. Taggart** 2000 – 2002  
Belfast

**Dr D. Raman** 1998 – 2000  
Sligo

**Dr A. Bell** 1996 – 1998  
Belfast

**Prof B. Bresnihan** RIP  
1994 – 1996 Dublin

**Prof M. Molloy** 1992 – 1994  
Dublin

**Dr E. Casey** 1990 – 1992  
Dublin

**Dr. S. Roberts** 1988 – 1990  
Belfast

**Dr C. Barry** RIP  
1985 – 1987 Dublin

**Dr D. Roden** RIP  
1983 – 1985 Dublin

**Dr W. Boyd** RIP  
1981 – 1983 Belfast

**Dr T. Gregg** RIP  
1979 – 1981 Dublin

**Dr J. Molony** RIP  
1977 – 1979 Dublin

**Dr M. McMahon** RIP  
1975 – 1977 Cork

**Dr T. O'Reilly** RIP  
1973 – 1975 Dublin

## Young Investigator Award 2014

### Oral Presentation (14A160)

**Pseudostarvation by AMPK activator therapy is associated with reduced disease activity and downregulation of pro-inflammatory responses in Rheumatoid Arthritis (RA)**

L. Gallagher<sup>1</sup>, U. Fearon<sup>2</sup>, D.J. Veale<sup>2</sup>, D. Kane<sup>1</sup>, L.A. O'Neill<sup>3</sup>, R. Mullan<sup>1</sup>

<sup>1</sup>Department of Rheumatology, Tallaght Hospital and TCD, Dublin, Ireland

<sup>2</sup>Translational Rheumatology Research Group, St. Vincent's University Hospital, Dublin 4

<sup>3</sup>School of Biochemistry and Immunology, TCD, Dublin, Ireland

**Introduction:** Aerobic glycolysis (The Warburg Effect) is well documented in both tumour and inflammatory cell biology. It's pharmacological inhibition through AMP Kinase (AMPK) activation, reverses the Warburg effect, both restoring energy balance and ameliorating pro-inflammatory and anabolic cell pathways. An opportunity exists for AMPK activation as a treatment strategy in Rheumatoid Arthritis (RA).

**Aims/Background:** Metformin is a safe and well-tolerated anti-diabetic compound used worldwide to treat type 2 diabetes. Metformin directly acts both directly and indirectly to activate AMPK. The association of AMPK and effectiveness of Metformin as an anti-inflammatory mediator in RA was evaluated.

**Method:** Activated AMPK (P-AMPK) and inactive AMPK (AMPK) expression in K4 Synovial Fibroblasts (K4SF) protein lysates were analyzed (Immunoblotting and immunofluorescence). Synovial Tissue (RAST) from RA patients were stained for P-AMPK/AMPK. K4SF were stimulated with LPS/TNF $\alpha$  (10ng/ml) in the presence of AMPK activators Metformin (0.5–2mM). Supernatants were evaluated for IL-6/IL-8 by ELISA.

**Results:** P-AMPK expression was increased by Metformin (2mM), compared to basal unstimulated K4SF cells, by immunoblot and immunofluorescence. Immunohistochemistry analysis indicate P-AMPK is decreased or absent in RA patient tissue with high DAS28, but strongly present low DAS28 patients. In LPS/TNF stimulated K4SF, IL-6 and IL-8 production was significantly inhibited in the presence of Metformin in a dose-dependent manner.

**Conclusions:** AMPK activation is associated with reduced RA disease activity and down-regulation of pro-inflammatory effector responses. AMPK activating drugs, such as Metformin may be suitable as a safe and effective therapy in the treatment of RA.



# Efficacy still going strong five years on

monthly  
**Simponi**<sup>®</sup>  
golimumab



Indicated for the treatment of moderate to severe, active rheumatoid arthritis in adult patients in combination with MTX when response to DMARDs therapy, including MTX, has been inadequate.



Indicated for the treatment of active and progressive psoriatic arthritis in adult patients when the response to DMARDs has been inadequate.



Indicated for the treatment of severe, active ankylosing spondylitis in adult patients who have responded inadequately to conventional therapy.

**Simponi 50 mg, 100 mg Solution for Injection in pre-filled pen.**

**Simponi 50 mg Solution for Injection in pre-filled syringe (golimumab).**

**Prescribing Information** [Refer to full SPC text before prescribing Simponi (golimumab)]. **Indications:** Rheumatoid Arthritis (RA): Simponi, in combination with methotrexate (MTX), is indicated for the treatment of moderate to severe, active rheumatoid arthritis in adults when the response to disease-modifying anti-rheumatic drug (DMARD) therapy including MTX has been inadequate; the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with MTX. Simponi, in combination with MTX, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function; Psoriatic Arthritis (PsA): Simponi, alone or in combination with MTX, is indicated for the treatment of active and progressive PsA in adults when the response to DMARD therapy has been inadequate. Simponi has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function. Ankylosing Spondylitis (AS): Simponi is indicated for treatment of severe, active AS in adults who have responded inadequately to conventional therapy. Ulcerative colitis (UC): Simponi is indicated for treatment of moderately to severely active UC in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies. **Dosage and administration:** Simponi should be injected subcutaneously. Treatment should be initiated and supervised by qualified physicians experienced in the diagnosis and treatment of RA, PsA, AS or UC. After proper training in subcutaneous injection technique, patients may self-inject, if their physician deems it appropriate. RA: Simponi 50 mg given once a month, on the same date each month, concomitantly with MTX. PsA: Simponi 50 mg given once a month, on the same date each month, alone or in combination with MTX. AS: Simponi 50 mg given once a month, on the same date each month. Clinical response is usually achieved within 12-14 weeks of treatment (3 or 4 doses). Continued therapy should be reconsidered in patients who show no evidence of therapeutic benefit within this time period. In patients weighing more than 100 kg who do not achieve an adequate clinical response after 3 or 4 doses, increasing the dose of golimumab to 100 mg once a month may be considered, taking into account the increased risk of certain serious adverse reactions with the 100 mg dose compared with the 50 mg dose. UC: Patients weighing < 80 kg: Simponi given as an initial dose of 200 mg, followed by 100 mg at week 2, then 50 mg every 4 weeks. Patients weighing ≥ 80 kg: Simponi given as an initial dose of 200 mg, followed by 100 mg at week 2, then 100 mg every 4 weeks. During maintenance treatment, corticosteroids may be tapered, following clinical practice guidelines. Clinical response is usually achieved within 12-14 weeks of treatment (after 4 doses). Missed dose: If a patient forgets to inject Simponi on the planned date, the forgotten dose should be injected as soon as the patient remembers. The patient should be instructed not to inject a double dose. Older patients (≥ 65 years): no dose adjustment required. Paediatric patients (< 18 years) and patients with renal and hepatic impairment: Simponi is not recommended in these populations. **Contraindications:** Patients with a hypersensitivity to golimumab or any of the excipients; Patients with active tuberculosis (TB) or other severe infection such as sepsis and opportunistic in-

fections; patients with moderate or severe heart failure (NYHA class III/IV). **Precautions and Warnings:** Infections: Patients must be monitored closely for infection before, during and for 5 months after cessation of treatment. Exercise caution when considering Simponi in patients with chronic infection or a history of recurrent infection including use of concomitant immunosuppressive therapy. Simponi should not be given to patients with clinically important active infection. Patients should be advised of the potential risk factors. Bacterial infections (including sepsis and pneumonia), mycobacterial (including TB), invasive fungal and opportunistic infections, including fatalities, have been reported. There was a greater incidence of serious infections, including opportunistic infections and TB, in patients receiving golimumab 100 mg compared with patients receiving golimumab 50 mg. Serious infections have occurred in patients on concomitant immunosuppressive therapy that, in addition to their underlying disease, could predispose them to infection. There have been reports of active TB in patients receiving Simponi, including patients previously treated for latent TB. Patients should be evaluated for active or latent TB before Simponi treatment. All such tests should be recorded on the Patient Alert Card provided with the product. If active TB is diagnosed, treatment with Simponi should not be initiated. If latent TB is diagnosed, treatment with anti-TB therapy must be initiated before initiation of Simponi. Patients on Simponi should be monitored closely for signs and symptoms of active TB and advised to seek medical advice if signs and/or symptoms of TB appear. **Hepatitis B (HBV) reactivation:** Reactivation of HBV infection in patients receiving Simponi who were chronic carriers. Some cases had a fatal outcome. Patients should be tested for HBV infection before initiating treatment with Simponi. **Malignancies and lymphoproliferative disorders:** Caution is advised when considering Simponi treatment in patients with history of malignancy or continuing treatment in patients who develop a malignancy, additional caution should be exercised in patients with increased risk for malignancy due to heavy smoking. A risk for the development of malignancies in children and adolescents cannot be excluded. Rare cases, usually fatal, of hepatosplenic T-cell lymphoma (HSTCL) have been reported, the majority of cases occurred in adolescent and young males nearly all on concomitant treatment with azathioprine (AZA) or 6-mercaptopurine (6-MP). The potential risk with the combination of AZA or 6-MP and Simponi should be carefully considered. A risk for the development for HSTCL in patients treated with TNF-blockers cannot be excluded. Colon dysplasia/carcinoma - Screen for dysplasia in all patients with UC who are at increased risk or had a prior history for dysplasia or colon carcinoma. In newly diagnosed dysplasia patients the risks and benefits of continued Simponi use should be carefully assessed. Melanoma (all TNF-blocking agents including Simponi) and Merkel cell carcinoma (other TNF-blocking agents) have been reported, periodic skin examination is recommended, particularly for patients with risk factors for skin cancer. **Heart Failure:** Simponi should be used with caution in patients with mild heart failure (NYHA class I/II) and discontinued in the event of worsening symptoms of heart failure. **Neurological events:** Use of anti-TNF therapy, including Simponi, has been associated with cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of central nervous system demyelinating disorders, including multiple sclerosis and peripheral demyelinating disorders. Discontinuation of Simponi should be considered if these disorders develop. Carefully consider the benefits and risks before initiation of therapy in patients with a history of demye-



## The GO studies

Recently presented five-year data confirm good persistence, sustained efficacy and predictable tolerability across indications with Simponi<sup>1-3</sup>

Persistence with  
Simponi at 5 years

(Simponi 50mg and 100mg)



GO-FORWARD<sup>1</sup>

70%

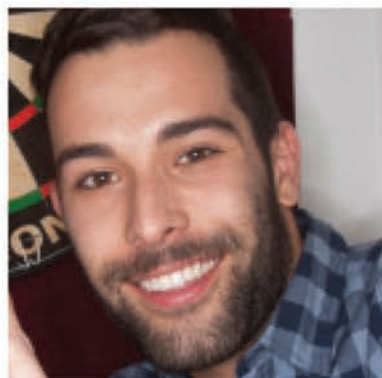
n=444



GO-REVEAL<sup>2</sup>

69%

n=405



GO-RAISE<sup>3</sup>

71%

n=356

linating disorders. **Surgery:** Patients requiring surgery whilst on Simponi therapy should be closely monitored for infections. **Autoimmune processes:** If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with Simponi and is positive for antibodies against double-stranded DNA, treatment should be discontinued. **Haematological reactions:** There have been post-marketing reports of pancytopenia, leucopenia, neutropenia, aplastic anaemia, and thrombocytopenia in patients receiving TNF-blockers. Cytopenias including pancytopenia have been reported infrequently in clinical trials. Patients should be advised to seek medical attention if they develop signs and symptoms suggestive of blood dyscrasias. Discontinuation should be considered in patients with significant haematologic abnormalities. **Vaccinations/therapeutic infectious agents:** It is recommended that live vaccines or any therapeutic infectious agents should not be given concurrently. **Allergic reactions:** If an anaphylactic reaction or other serious allergic reaction occurs, administration of Simponi should be discontinued immediately, and suitable treatment initiated. The needle cover of the pre-filled pen contains latex and may cause allergic reactions in those sensitive to latex. **Special populations:** Adverse events, serious adverse events and serious infections in patients aged ≥65 were comparable to those observed in younger patients. However, caution should be exercised when treating the elderly, particular attention should be paid to infections. Simponi contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take Simponi. **Interactions:** Combination of Simponi and other biological therapeutics used to treat the same conditions as Simponi, including anakinra and abatacept is not recommended. **Pregnancy and Lactation:** Administration of Simponi is not recommended during pregnancy or breast-feeding. Women of childbearing potential should use adequate contraception and continue its use for at least 6 months after the last Simponi treatment. **Side-effects:** Refer to SmPC for complete information on side effects. **Very Common (≥ 1/10):** upper respiratory tract infection; **Common (≥ 1/100):** bacterial infections, lower respiratory tract infections, viral infections, bronchitis, sinusitis, superficial fungal infections, abscess, anaemia, allergic reactions, autoantibody positive, dizziness, headache, paraesthesia, hypertension, asthma and related symptoms, dyspepsia, gastrointestinal and abdominal pain, nausea, gastrointestinal inflammatory disorders, stomatitis, alanine aminotransferase increased, aspartate aminotransferase increased, pruritus, rash, alopecia, dermatitis, pyrexia, asthenia and injection site reaction, chest discomfort, were reported. Serious, including fatal adverse events have been reported including septic shock, lymphoma, leukaemia, melanoma, Merkel cell carcinoma\*, hepatosplenic T-cell lymphoma\*, leucopenia, thrombocytopenia, pancytopenia, aplastic anaemia, serious systemic hypersensitivity reactions (including anaphylactic reaction), skin exfoliation, vasculitis (systemic), sarcoidosis, demyelinating disorders, congestive heart failure, arrhythmia, ischaemic coronary artery disease, thrombosis, Interstitial lung disease and lupus-like syndrome. \*Observed with other TNF-blocking agents, but not observed in clinical studies with golimumab. **Package quantities:** 1 50 mg pre-filled pen containing 50 mg of golimumab in 0.5 ml solution for injection or 1 50 mg pre-filled syringe containing 50 mg of golimumab in 0.5 ml solution for injection or 1 100 mg pre-filled pen containing 100 mg of golimumab in 1 ml solution for injection. **Legal Category:** Prescription Only Medicine. **Marketing Authorisation Number:** 50 mg Pre-filled Pen EU/1/09/546/001; 50 mg Pre-filled Syringe EU/1/09/546/003; 100 mg Pre-filled Pen EU/1/09/546/005.

**Marketing Authorisation Holder:** Janssen Biologics B.V., Einsteinweg 101, 2333 CB Leiden, The Netherlands. **Date of Revision of Text:** February 2015. © Merck Sharp & Dohme Ireland (Human Health) Limited, 2015. All rights reserved. **Further information is available on request from:** MSD, Red Oak North, South County Business Park, Leopardstown, Dublin 18 or from [www.medicines.ie](http://www.medicines.ie). **Date of preparation:** March 2015.

Adverse events should be reported. Reporting forms and information can be found at [www.hpra.ie](http://www.hpra.ie)  
Adverse events should also be reported to MSD (Tel: 01-299 8700)

### References

1. Keystone E et al. Presented at EULAR 2013 Congress, Madrid, Spain, June 12-15, 2013. Abstract AB0267.
2. Kavanaugh A, McInnes IB, Mease P, et al. Clinical efficacy, radiographic and safety findings through 5 years of subcutaneous golimumab treatment in patients with active psoriatic arthritis: results from a long-term extension of a randomised, placebo-controlled trial, the GO-REVEAL study. *Ann Rheum Dis*. Published Online First: 19 April 2014, doi:10.1136/annrheumdis-2013-204902. Supplemental content: 1-15.
3. Deodhar A, et al. Golimumab Administered Subcutaneously Every 4 Weeks in Ankylosing Spondylitis: 5-year Results of the GO-RAISE Study published online 11NOV14 doi:10.1136/annrheumdis-2014-205862.



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# Introducing A NOVEL ORAL THERAPY THAT MAY CHANGE THE WAY YOU TREAT PSORIATIC ARTHRITIS



- ◆ Proven efficacy in clinical trials vs. placebo<sup>1</sup>
- ◆ Favourable safety profile with no increased risk of malignancy, serious infection, or tuberculosis vs. placebo, demonstrated in clinical trials<sup>1,2</sup>
- ◆ Oral dosing<sup>1</sup>
- ◆ No requirement for tuberculosis prescreening or any ongoing laboratory monitoring<sup>1,2</sup>

## INDICATION

Otezla, alone or in combination with Disease Modifying Antirheumatic Drugs (DMARDs), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy.<sup>1</sup>



**Prescribing Information: Otezla® (apremilast) 10mg, 20mg and 30mg film coated-tablets.**

Refer to the Summary of Product Characteristics (SPC) before prescribing.

**Presentation:** 10mg, 20mg and 30mg film coated-tablets. **Indications:** Psoriatic arthritis: Otezla®, alone or in combination with Disease Modifying Antirheumatic Drugs (DMARDs), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy. **Psoriasis:** Otezla® is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or psoralen and ultraviolet-A light (PUVA). **Dosage and administration:** Treatment with Otezla® should be initiated by specialists experienced in the diagnosis and treatment of psoriasis or psoriatic arthritis. The recommended dose of Otezla® is 30mg twice daily taken orally, morning and evening, approximately 12 hours apart, with no food restrictions. The film-coated tablets should be swallowed whole. To reduce risk of gastrointestinal symptoms, an initial dose titration is required according to the following schedule: Day 1: 10mg in morning; Day 2: 10mg in morning and 10mg in evening; Day 3: 10mg in morning and 20mg in evening; Day 4: 20mg in morning and 20mg in evening; Day 5: 20mg in morning and 30mg in evening; Day 6 and thereafter: 30mg twice daily. No re-titration is required after initial titration. If patients miss a dose, the next dose should be taken as soon as possible. If it is close to the time for their next dose, the missed dose should not be taken and the next dose should be taken at the regular time. During pivotal trials the greatest improvement

was observed within the first 24 weeks of treatment. If a patient shows no evidence of therapeutic benefit after 24 weeks, treatment should be reconsidered. The patient's response to treatment should be evaluated on a regular basis. Clinical experience beyond 52 weeks is not available in psoriasis. **Special populations:** Paediatric population: The safety and efficacy of apremilast in children aged 0 to 17 years have not been established. No data are available. **Elderly patients:** No dose adjustment is required for this patient population. **Patients with renal impairment:** No dose adjustment is needed in patients with mild and moderate renal impairment. The dose of apremilast should be reduced to 30mg once daily in patients with severe renal impairment (creatinine clearance of less than 30mL per minute estimated by the Cockcroft-Gault equation). For initial dose titration in this group, it is recommended that Otezla® be titrated using only the morning doses and the evening doses be skipped. **Patients with hepatic impairment:** No dose adjustment is necessary for patients with hepatic impairment. **Contraindications:** Hypersensitivity to the active substance(s) or to any of the following excipients: Microcrystalline cellulose, Lactose monohydrate, Croscarmellose sodium, Magnesium stearate, Polyvinyl alcohol, Titanium dioxide (E171), Macrogol 3350, Talc, iron oxide red (E172). The 20mg tablets also contain iron oxide yellow (E172). The 30mg tablets also contain iron oxide yellow (E172) and iron oxide black (E172). Otezla® is contraindicated in pregnancy and should be excluded before treatment can be initiated. **Special warnings and precautions:** Patients with rare hereditary problems of galactose intolerance, lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. Otezla® should be dose reduced to 30mg once daily in patients with severe renal impairment. Apremilast

may cause weight loss. Patients who are underweight at the start of treatment should have their body weight monitored regularly. In the event of unexplained and clinically significant weight loss, these patients should be evaluated by a medical practitioner and discontinuation of treatment should be considered. Women of childbearing potential should use an effective method of contraception to prevent pregnancy during treatment. Apremilast should not be used during breast-feeding. No fertility data is available in humans. **Interactions:** Co-administration of strong cytochrome P450 3A4 (CYP3A4) enzyme inducers, rifampicin, resulted in a reduction of systemic exposure of apremilast, which may result in a loss of efficacy of apremilast. Therefore, the use of strong CYP3A4 enzyme inducers (e.g. rifampicin, phenobarbital, carbamazepine, phenytoin and St. John's Wort) with apremilast is not recommended. In clinical studies, apremilast has been administered concomitantly with topical therapy (including corticosteroids, coal tar shampoo and salicylic acid scalp preparations) and UVB phototherapy. There was no clinically meaningful drug-drug interaction between ketoconazole and apremilast. Apremilast can be co-administered with a potent CYP3A4 inhibitor such as ketoconazole. There was no pharmacokinetic drug-drug interaction between apremilast and methotrexate in psoriatic arthritis patients. Apremilast can be co-administered with methotrexate. There was no pharmacokinetic drug-drug interaction between apremilast and oral contraceptives containing ethinyl estradiol and norgestimate. Apremilast can be co-administered with oral contraceptives. **Side effects:** The most commonly reported adverse reactions in Phase III clinical studies have been gastrointestinal disorders including diarrhoea and nausea. The other most commonly reported adverse reactions included upper respiratory tract infections, headache,

and tension headache. The most common adverse reactions leading to discontinuation during the first 16 weeks of treatment were diarrhoea, and nausea. The overall incidence of serious adverse reactions was low and did not indicate any specific system organ involvement. Prescribers should consult the summary of product characteristics in relation to other side-effects. **NHS list price:** £265.18 per 14 day titration pack; £550 per pack of 56 tablets (30mg). **Legal category:** POM. **Marketing authorisation numbers:** EU/1/14/981/001, EU/1/14/981/002 and EU/1/14/981/003. **Marketing authorisation holder:** Celgene Ltd, 1 Longwalk Road, Stockley Park, Uxbridge, UB11 1DB, United Kingdom. **Date of preparation:** January 2015. **Approval code:** UK-18140098.

Adverse events should be reported. Reporting forms and information can be found at [www.yellowcard.mhra.gov.uk](http://www.yellowcard.mhra.gov.uk). Adverse events should also be reported to Celgene Drug Safety Tel: 0800 238 9908; Fax: 0844 801 0468

**References:**  
1. Otezla Summary of Product Characteristics available at [www.medicines.org.uk](http://www.medicines.org.uk)  
2. Mease PJ, et al. Poster 310 presented at the Annual Meeting of ACR/ARHP, San Diego, California, October 26-30, 2013.  
**Date of Preparation:** February 2015 **UK-18140071b**





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# Adenuric<sup>®</sup>

(febuxostat)

## Treat to target. Daily.<sup>1</sup>

**ADENURIC 80 mg and 120 mg film-coated tablets: Abbreviated Prescribing Information** Please consult the Summary of Product Characteristics (SmPC) for full prescribing information.

**Presentation:** Film-coated tablets containing 80 mg or 120 mg febuxostat. Also contains lactose monohydrate. **Use:** Treatment of chronic hyperuricaemia in conditions where urate deposition has already occurred (including a history, or presence of, tophus and/or gouty arthritis) in adults.

**Dosage and administration:** Oral use with or without food. Recommended dose is 80 mg once daily. If serum uric acid is > 6 mg/dL (357 µmol/L) after 2-4 weeks, 120 mg once daily may be considered. **Elderly people:** No dose adjustment required. **Renal impairment:** No dosage adjustment necessary in patients with mild or moderate renal impairment. Efficacy and safety not fully evaluated in patients with severe renal impairment. **Hepatic impairment:** Recommended dosage in patients with mild hepatic impairment is 80 mg. Limited information available in patients with moderate hepatic impairment. Efficacy and safety has not been studied in patients with severe hepatic impairment. **Children and adolescents:** Safety and efficacy in children under 18 has not been established. **Organ transplant recipients:** No experience therefore not recommended. **Contraindications:** Hypersensitivity to the active ingredient or to any of the excipients. **Warnings and precautions:** **Cardio-vascular disorders:** **Not recommended in patients with ischaemic heart disease or congestive heart failure.** **Product allergy/hypersensitivity:** Advise patients of signs/symptoms of allergic/hypersensitivity reactions and monitor closely for symptoms. Stop treatment immediately if serious reactions occur, including Stevens-Johnson syndrome, Toxic epidermal necrolysis and acute anaphylactic reaction/shock; do not re-start febuxostat at any time. Severe hypersensitivity reactions, including Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) associated with fever, haematological, renal or hepatic involvement in some cases. **Acute gouty attacks (gout flare):** Do not start treatment until an acute attack of gout has completely subsided. As with other urate lowering medicinal products, gout flares may occur during initiation of treatment. At treatment initiation flare prophylaxis for at least 6 months with an NSAID or colchicine is recommended. If a gout flare occurs during treatment, do not discontinue. Manage the gout flare concurrently as appropriate. Continuous treatment decreases frequency and intensity of gout flares. **Xanthine deposition:** As with other urate lowering medicinal products, in patients in whom the rate of urate formation is greatly increased (e.g. malignant disease and its treatment, Lesch-Nyhan syndrome), the absolute concentration of xanthine in urine could, in rare cases, rise sufficiently to allow deposition in the urinary tract. As there has been no experience, febuxostat is not recommended for use in these populations. **Mercaptopurine/azathioprine:** Not recommended in patients concomitantly treated with mercaptopurine/azathioprine. Where combination cannot be avoided, monitor patients closely. Dose reduction for mercaptopurine/azathioprine is recommended. **Theophylline:** No pharmacokinetic interaction shown with febuxostat 80 mg, no data for 120 mg. **Liver disorders:** Liver function test is recommended prior to the initiation of therapy and periodically thereafter based on clinical judgement. **Thyroid disorders:** Caution in patients with alteration of thyroid function. **Lactose:** Contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. **Interactions:** **Mercaptopurine/azathioprine:** On the basis of the mechanism of action of febuxostat on xanthine oxidase inhibition concomitant use is not recommended. No data is available regarding the safety of febuxostat during cytotoxic chemotherapy. **Rosiglitazone/CYP2C8 inhibitors:** No dosage adjustment required. **Theophylline:** No special caution advised for 80 mg febuxostat, no data available for 120 mg. **Naproxen and other inhibitors of glucuronidation:** Can be co-administered with naproxen with no dose adjustments necessary. **Inducers of glucuronidation:** Monitoring of serum uric acid is recommended 1-2 weeks after start of treatment with a potent inducer of glucuronidation. Cessation of treatment of an inducer might lead to increased plasma levels of

febuxostat. **Colchicine/indometacin/hydrochlorothiazide/warfarin:** Can be co-administered with colchicine or indometacin with no dose adjustments necessary. No dose adjustment necessary when administered with hydrochlorothiazide. No dose adjustment necessary for warfarin when administered with febuxostat. **Desipramine/CYP2D6 substrates:** Co administration with other CYP2D6 substrates is not expected to require any dose adjustment for those compounds. **Antacids:** May be taken without regard to antacid use. **Pregnancy and lactation:** Do not use during pregnancy or breast-feeding. Effect on fertility unknown. **Side-Effects:** **Clinical Studies and post-marketing experience:** **Common (1-10%):** Gout flares, headache, diarrhoea\*, nausea, liver function test abnormalities\*, rash, oedema. **Uncommon (0.1-1%):** Blood thyroid stimulating hormone increased, diabetes mellitus, hyperlipidemia, decrease appetite, weight increase, decreased libido, insomnia, dizziness, paraesthesia, hemiparesis, somnolence, altered taste, hypoaesthesia, hyposmia, atrial fibrillation, palpitations, ECG abnormal, hypertension, flushing, hot flush, dyspnoea, bronchitis, upper respiratory tract infection, cough, abdominal pain, abdominal distension, gastro-oesophageal reflux disease, vomiting, dry mouth, dyspepsia, constipation, frequent stools, flatulence, gastrointestinal discomfort, cholelithiasis, dermatitis, urticaria, pruritus, skin discolouration, skin lesion, petechiae, rash macular, rash maculopapular, rash papular, arthralgia, arthritis, myalgia, musculoskeletal pain, muscle weakness, muscle spasm, muscle tightness, bursitis, renal failure, nephrolithiasis, haematuria, pollakiuria, proteinuria, erectile dysfunction, fatigue, chest pain, chest discomfort, blood amylase increase, platelet count decrease, WBC decrease, lymphocyte count decrease, blood creatine increase, blood creatinine increase, haemoglobin decrease, blood urea increase, blood triglycerides increase, blood cholesterol increase, haematocrit decrease, blood lactate dehydrogenase increased, blood potassium increase. **Rare (0.1-0.01%):** Pancytopenia, thrombocytopenia, anaphylactic reaction\*\*, drug hypersensitivity\*\*, blurred vision, weight decrease, increase appetite, anorexia, nervousness, linnitus, pancreatitis, mouth ulceration, hepatitis, jaundice\*\*, liver injury\*\*, Toxic epidermal necrolysis\*\*, Stevens-Johnson Syndrome\*\*, DRESS\*\*, angioedema\*\*, generalized rash (serious)\*\*, erythema, exfoliative rash, rash follicular, rash vesicular, rash pustular, rash pruritic\*\*, rash erythematous, rash morbilliform, alopecia, hyperhidrosis, rhabdomyolysis\*\*, joint stiffness, musculoskeletal stiffness, tubulointerstitial nephritis\*\*, micturition urgency, thirst, blood glucose increase, activated partial thromboplastin time prolonged, red blood cell count decrease, blood alkaline phosphatase increase. \*Treatment-emergent non-infective diarrhoea and abnormal liver function tests in combined Phase III studies more frequent in patients concomitantly treated with colchicine. \*\*Adverse reactions coming from post-marketing experience. Rare serious hypersensitivity reactions including Stevens-Johnson Syndrome and anaphylactic reaction/shock have occurred in post-marketing experience. Hypersensitivity reactions to febuxostat can be associated with the following symptoms: skin reactions characterised by infiltrated maculopapular eruption, generalised or exfoliative rashes, also skin lesions, facial oedema, fever, haematologic abnormalities such as thrombocytopenia, and single or multiple organ involvement (liver and kidney including tubulointerstitial nephritis). Gout flares commonly observed soon after treatment start and in first months. Frequency decreases after time. Gout flare prophylaxis is recommended. Please consult the SmPC for further information. **Pack sizes:** 80 mg and 120 mg tablets: 28 film-coated tablets. **Legal category:** POM. **Marketing authorization number:** EU/1/08/447/001 & 003. **Marketing authorization holder:** Menarini International Operations Luxembourg S.A., Avenue de la Gare, L-1611 Luxembourg, Luxembourg. **Marketed by:** A. Menarini Pharmaceuticals Ireland Ltd. Further information is available on request to A. Menarini Pharmaceuticals Ireland Ltd, 2nd Floor, Castlecourt, Monkstown Farm, Monkstown, Glenageary, Co. Dublin or may be found in the SmPC. **Last updated:** March 2014. **Reference:** 1. Adenuric SmPC, March 2014.

ADENURIC<sup>®</sup> is a trademark of Teijin Limited, Tokyo, Japan

Date of item: January 2015  
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## IRHPS Spring 2015 Update

### Welcome to the Spring Conference 2015.

Firstly I would like to extend my thanks to the ISR, Michael and Jenny, and also to the Pharma companies for their continued support towards a wide range of educational opportunities through our various bursaries.

We had a very successful meeting in Killiney last September with presentations from Dr. Charlene Foley, Our Lady's Children's Hospital Crumlin and Dr. Brian Maguire, NUI Galway. Dr. Foley presented on the Arthropathy of Down syndrome. Dr. Maguire presented on Arthritis and Pain Management.

The two highest scoring IRHPS abstract submissions also presented their work. Congratulations to Catherine Cullinane, Senior Physiotherapist, University Hospital Waterford, winner of the Professor Barry Bresnihan gold medal award and Paul Kirwan, Senior Physiotherapist, Connolly Hospital who claimed the silver prize. Both are pictured with representatives from Abbvie who sponsored these awards.

Other awards included the Roche poster awards. The prize winners were Noreen Walsh and Noreen Lennox who have won the opportunity to attend EULAR in Rome 2015. The UCB poster award winners were Oriel Corcoran, Sarah O'Driscoll, Derek Deely, Helen Reynolds and Maura McGreeney. The people's choice award went to Una Martin.

This year we will be contacting you to submit your opinions on topics you would like covered at our future meetings. Remember to keep an eye on our website [www.irhps.ie](http://www.irhps.ie) for news on meetings and educational awards.

Finally a huge thanks must go to our outgoing chair Rhona Galway for her dedication and endless hard work, not only in her role as chair but as a committee member of the IRHPS committee for many years.

**DEREK DEELY**  
IRHPS Chair



L-R: David Lynch (Abbvie), Paul Kirwin, Dan Duffy (Abbvie), Rhona Galway, Catherine Cullinane.



L-R: Eimear Lyons, Dr. Brian Maguire, Dr. Charlene Foley, Derek Deely.



Noreen Lennox, Oriel Corcoran; Bindu Irudayaraj, Rhona Galway, Derek Deely, Eileen O'Flynn, Una Martin & Catherine Cullinane





# A different journey is possible

Inhibit  
radiographic  
progression<sup>1</sup>

Improve  
physical function<sup>1</sup>

Reduce joint and  
skin symptoms<sup>1</sup>

## Psoriatic arthritis<sup>1</sup>

HUMIRA is indicated for the treatment of active and progressive psoriatic arthritis in adults when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate. HUMIRA has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function.

**References:** 1. HUMIRA [summary of product characteristics]. AbbVie Ltd.

Full prescribing information is available upon request from AbbVie Limited, Block B, Liffey Valley Office Campus, Quarryvale, Co Dublin, Ireland. **Legal category:** POM. **Marketing Authorisation Numbers:** EU/1/03/256/002-005, EU/1/03/256/007-010. **Marketing Authorisation Holder:** AbbVie Ltd., Maidenhead, Berkshire SL6 4XE, UK.

abbvie

Date of Preparation: February 2015 IREHUR140436b

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# ISR Autumn 2014

Thursday 11th September - Scientific Oral Papers



Welcome by ISR President: Prof David Kane



Dr Ursula Fearon & Prof Gerry Wilson



Dr Wei Gao



Dr Lorraine O'Neill



Dr Eoghan McCarthy



Dr Sian Cregan

Thursday 11th September - Session 1 - Rheumatoid Arthritis



Dr Eimear Linehan



Dr Kimme Hyrich (Centre for Musculoskeletal Research-Manchester, UK) – 'Lessons from British biologics registry'



Prof Steffan Gay (University Hospital Zurich, Switzerland) 'Epigenetics in the pathogenesis of rheumatic diseases'



# RUN, JOG OR WALK

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**Arthritis Ireland**  
Little Things make a Big Difference

## Join the **Arthritis Ireland** team for the **2015 Women's** **Mini Marathon** on **June 1<sup>st</sup>** in Dublin.

Raise badly needed funds so that we can continue to provide support, information & services to those living with arthritis and their families.

Register today at the Arthritis Ireland stand, visit [www.arthritisireland.ie](http://www.arthritisireland.ie) or call Orla on 01-647 0209 to receive your pack.



## Join our team of doctors, researchers and patients and cycle 100km to help find a cure for arthritis.

Take part in the second  
**Working on a Cure Cycle**  
in Wicklow on June 7<sup>th</sup> and  
raise vital funds to support  
ongoing research.

Register today at the Arthritis Ireland stand, visit [www.arthritisireland.ie](http://www.arthritisireland.ie) or call Orla on 01-647 0209 to receive your pack.



**WORKING  
ON A CURE  
CYCLE**



# ISR Autumn 2014

## Clinical Oral Papers, Thursday 11th September



Dr Suzanne Donnelly & Dr Eamonn Molloy



Dr David McCormick



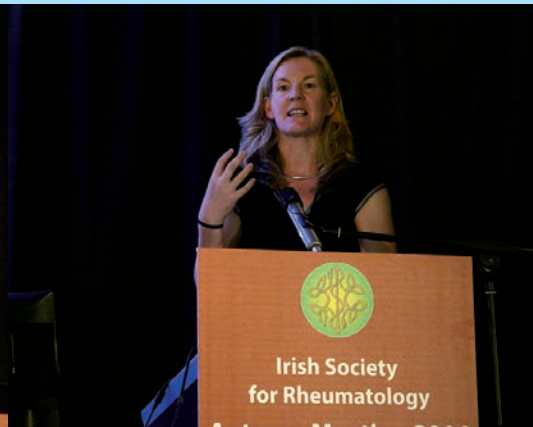
Dr S A Ramakrishnan



Dr Lorraine O'Neill

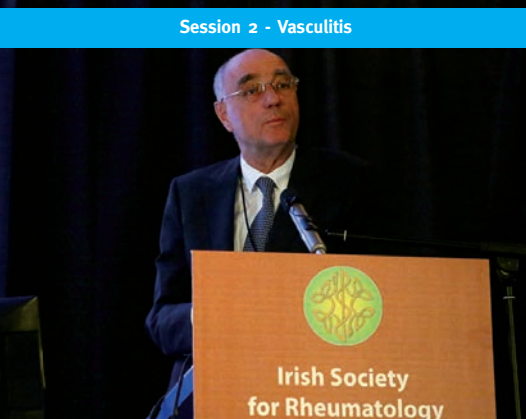


Dr Aamir Saeed



Dr Helen French

## Session 2 - Vasculitis



Prof Wolfgang Gross (University Hospital Schleswig-Holstein, Campus Lubeck, Germany) – 'ANCA associated vasculitis: New perspectives on pathogenesis'



Dr David Jayne (University of Cambridge, UK) – 'Advances in treatment of ANCA associated vasculitis'

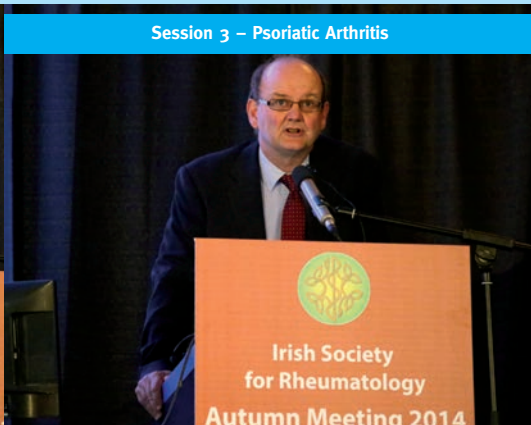


Dr Philip Gardiner & Prof Oliver FitzGerald

## Friday 12th September



Prof Gerry Wilson & John Church  
Arthritis Ireland presentation 'Planning for the future'



Prof Neil McHugh (Pharmacoepidemiology – University of Bath, UK) – 'Psoriatic Arthritis – the need for early intervention'



Prof Robert Winchester (College of Physicians & Surgeons – Columbia, NY) – 'Clinical Phenotype in Spondyloarthritis: is it all in the genes?'





## ...Committed to our future





## Reception & Dinner: Thurs 11th September, 2014



Mrs Gross; Prof Wolfgang Gross; Prof Robert Winchester & Prof Neil McHugh



Philip Gardiner & Esme Whitehead



Maria Wray, Gary Wright & Elisabeth Ball



Cathy Donaghy, Emma Mack, Anne-Marie McShane & Claire Masih



Stephen McDonald, Roger Stewart, & David McCormick



Hugh Sheehan (Abbvie), Ann McDermott & Brian Whately (TCP Homecare)



Frances Galvin (Roche), Claire-Louise Murphy, Michele Doran & Rose Brady (Roche)



Eimear Linehan, Prof Steffan Gay, Doug Veale, Ursula Fearon & Trudy McGarry



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Change your perception. Choose INFLECTRA™.

## Abbreviated Indications:

**Rheumatoid arthritis (RA):** in combination with MTX, for reducing the signs and symptoms of RA and to improve physical function in: adult patients with active disease when the response to DMARDs, including MTX, has been inadequate; adult patients with severe, active and progressive disease not previously treated with MTX or other DMARDs.

**Ankylosing spondylitis (AS):** adult patients with severe, active AS who have responded inadequately to conventional treatment.

**Psoriatic arthritis (PsA):** adult patients with active and progressive PsA when the response to previous DMARD therapy has been inadequate: in combination with MTX; or alone in patients who show intolerance to MTX or for whom MTX is contraindicated.



## Abbreviated Prescribing Information – INFLECTRA™ (Infliximab) powder for concentrate for solution for infusion

Please refer to full Summary of Product Characteristics (SmPC) before prescribing. **Presentation:** Vial containing 100 mg of infliximab powder for concentrate for solution for infusion. **Indications:** 1) *Rheumatoid arthritis* in adult patients with active disease with inadequate response to disease-modifying antirheumatic drugs (DMARDs) or adult patients with severe, active and progressive disease not previously treated with methotrexate (MTX) or other DMARDs 2) *Adult Crohn's disease* a) In patients with moderately to severely active Crohn's disease who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant to or have contraindications for such therapies. b) In patients with fistulising, active Crohn's disease who have not responded despite conventional treatment (including antibiotics, drainage and immunosuppressive therapy). 3) *Paediatric Crohn's disease* Severe, active Crohn's disease in patients aged 6 to 17 years, who have not responded to conventional therapy including corticosteroid, immunomodulator and primary nutrition therapy; or who are intolerant to or have contraindications for such therapies. 4) *Ulcerative colitis* In both adult patients with moderate to severely active ulcerative colitis, and children and adolescents aged 6 to 17 years with severely active ulcerative colitis and an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine or azathioprine; or who are intolerant to or have contraindications for such therapies. 5) *Ankylosing spondylitis* In adult patients with severe active ankylosing spondylitis who have responded inadequately to conventional therapy. 6) *Psoriatic arthritis* In adult patients with active and progressive psoriatic arthritis when response to previous DMARD therapy has been inadequate. 7) *Psoarthritis* In adult patients with moderate to severe plaque psoriasis who failed to respond to, or who have a contraindication to, or are intolerant to systemic therapy including cyclosporine, MTX or PUVA. **Dosage & Administration** 1) *Rheumatoid arthritis* 3 mg/kg as an intravenous (IV) infusion repeated 2 and 6 weeks after initiation, then every 8 weeks. Inflectra must be given concomitantly with MTX. 2) *Moderately to severely active Crohn's disease* 5 mg/kg IV infusion repeated 2 weeks after initiation. If a patient does not respond after 2 doses, no additional dose should be given. 3) *Fistulising, active Crohn's disease* 5 mg/kg IV infusion repeated 2 and 6 weeks after initiation. If a patient does not respond after 3 doses, no additional dose should be given. 4) *Ulcerative colitis* 5 mg/kg IV infusion repeated 2 and 6 weeks after initiation, then every 8 weeks. 5) *Ankylosing spondylitis* 5 mg/kg IV infusion repeated 2 and 6 weeks after initiation, then every 6 to 8 weeks. If a patient does not respond by 6 weeks, no additional dose should be given. 6) *Psoriatic arthritis* 5 mg/kg IV infusion repeated at 2 and 6 weeks after initiation, then every 8 weeks. 7) *Psoarthritis* 5 mg/kg IV infusion repeated 2 and 6 weeks after initiation, then every 8 weeks. If a patient shows no response after 14 weeks no additional dose should be given. Administer IV over 2 hours initially and monitor for infusion-related reactions.

**Contraindications:** Hypersensitivity to infliximab, to other murine proteins, or to any excipients. Tuberculosis (TB) or other severe infections such as sepsis, abscesses, and opportunistic infections. Moderate or severe heart failure (NYHA class III/IV). **Warnings and Precautions:** Caution in patients with or at risk of infusion reactions and hypersensitivity. Do not administer in patients with infections, and/or invasive fungal infections. Monitor for TB and do not use in patients with TB. Test for latent/active TB prior to initiation of therapy. Do not use Inflectra in patients with active TB, patients with latent TB must not be initiated on Inflectra therapy until initiation with anti-TB therapy. Monitor closely for infections, including TB before, during and for six months post-treatment. Patients with fistulising Crohn's disease with acute suppurative fistulas must not initiate therapy until source of infection, specifically abscess, is excluded. Test for HBV infection before initiating treatment. Consult expert in treatment for HBV-positive patients. Closely monitor carriers of HBV during and after therapy. In patients with HBV reactivation, stop Inflectra and initiate appropriate therapy. Pregnancy should be avoided during therapy, and for at least 6 months after last infusion. **Adverse effects:** Viral infection, bacterial infection, TB, fungal infection, meningitis, opportunistic infection, parasitic infection, hepatitis B reactivation, lymphoma, non-Hodgkin's lymphoma, Hodgkin's disease, leukaemia, melanoma, hepatosplenic T-cell lymphoma, Merkel cell carcinoma, allergic respiratory symptom, anaphylactic reaction/shock, lupus like syndrome, serum sickness-like reaction, vasculitis, sarcoid-like reaction, depression, insomnia, amnesia, agitation, confusion, somnolence, nervousness, apathy, headache, vertigo, dizziness, hypoaesthesia, paraesthesia, seizure, neuropathy, transverse myelitis, demyelinating disorders, conjunctivitis, keratitis, periorbital oedema, hordeolum, endophthalmitis, transient visual loss, tachycardia, palpitation, cardiac failure, arrhythmia, syncope, bradycardia, cyanosis, pericardial effusion, myocardial ischaemia/infarction, hypotension, hypertension, ecchymosis, hot flush, flushing, peripheral ischaemia, thrombophlebitis, haematoma, circulatory failure, petechia, vasospasm, URTI, sinusitis, lower respiratory tract infection, dyspnoea, epistaxis, pulmonary oedema, bronchospasm, pleurisy, pleural effusion, interstitial lung disease, abdominal pain, nausea, gastrointestinal haemorrhage, diarrhoea, dyspepsia, gastroesophageal reflux, constipation, intestinal perforation/stenosis, diverticulitis, pancreatitis, chelitis, hepatic function abnormal, transaminases increased, hepatitis, hepatocellular damage, cholecystitis, jaundice, liver failure, psoriasis (new onset or worsening), urticaria, rash, pruritus, hyperhidrosis, dry skin, fungal dermatitis, eczema, alopecia, bullous eruption, onychomycosis, seborrhoea, rosacea, skin papilloma, hyperkeratosis, abnormal skin pigmentation, Toxic Epidermal Necrolysis, Stevens-Johnson syndrome, erythema multiforme, furunculosis, arthralgia, myalgia, back pain, urinary tract infection, pyelonephritis, vaginitis, infusion related reaction, pain, chest pain, fatigue, fever, injection site reaction, chills, oedema, impaired healing, granulomatous lesion, autoantibody positive, complement factor abnormal. The SmPC should be consulted for further details of adverse effects **Legal**

category: POM Marketing Authorisation Number/Pack: EU/1/13/854/001 (1 vial); EU/1/13/854/002 (2 vials); EU/1/13/854/003 (3 vials); EU/1/13/854/004 (4 vials); EU/1/13/854/005 (5 vials) **Marketing Authorisation Holder:** Hospira UK Limited, Queensway, Royal Leamington Spa, CV31 3RW. Further information is available on request from: Hospira Ireland Ltd, Unit 15, The Park, The Hyde Building, Carrickmores, Dublin 18, Ireland **Date of preparation:** October 2013 (IE/INF/13/0003)

Adverse events should be reported. Reporting forms and information can be found at [www.imb.ie](http://www.imb.ie)  
Adverse events should also be reported to Hospira UK Ltd.  
Telephone Medical Information: +44 (0) 1926 834400

MTX = Methotrexate  
DMARD = Disease-modifying anti-rheumatic drug

## References:

1. INFLECTRA™. European Public Assessment Report (EPAR). Available at: [www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002778/human\\_med\\_001677.jsp&mid=WC0b01ac058001d124](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002778/human_med_001677.jsp&mid=WC0b01ac058001d124). [Accessed January 2014]. 2. EMA. Guideline on similar biological medicinal products containing monoclonal antibodies – non-clinical and clinical issues. May 2012. Available at: [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2012/06/WC500128686.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/06/WC500128686.pdf) [Accessed January 2014].

IE/INF/14/0002  
January 2014

  
**Hospira**  
**Biologics**

BioLogical Confidence



## Reception & Dinner: Thurs 11th September, 2014



Included at the main table are: top left, Adrian Pendleton and Sinead Harney, top right, Tom Moloney, Prof. Neil McHugh, Prof. Oliver FitzGerald, Prof. Robert Winchester



Included at the main table are: left, Eamonn Malloy, Donough Howard, Gary Wright & David Kane, right, Sandy Fraser, Suzanne Donnelly & Ursula Fearon



Gerard Walshe (Roche), Bobby Coughlan, Geraldine Mannion



ISR President speaking at the Gala Dinner



Steve Arnold (UCB - MD), Mike Arnold (UCB), Lorraine O'Neill, Claire-Louise Murphy & Eoghan McCarthy



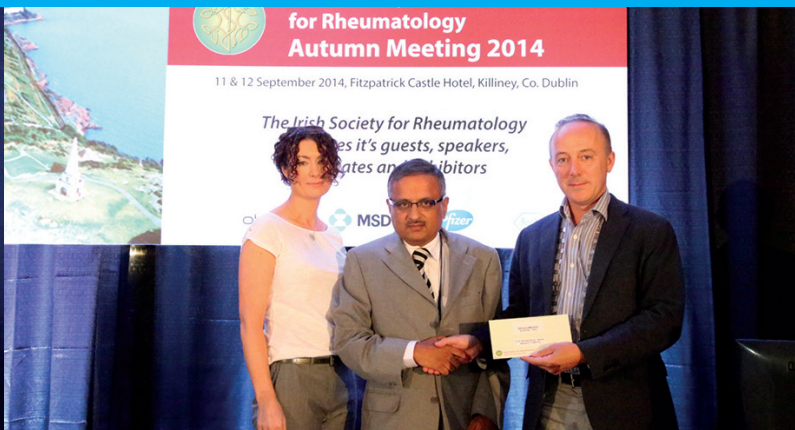
Grainne O'Leary (AI), John Church (CEO: AI), Emma Barrett, Eimear Linehan, Trudy McGarry, Sian Cregan, Michelle Trenkmann



# Prize Winners: ISR Autumn 2014



1st prize Oral: awarded to Sian Cregan (UCD) by Rose Brady (Roche) & Prof David Kane (ISR President)



2nd prize Oral: awarded to Dr S A Ramakrishnan (Navan) by Rose Brady (Roche) & Prof David Kane (ISR President)



3rd prize Oral: awarded to Dr Wei Gao (SVUH) by Rose Brady (Roche) & Prof David Kane (ISR President)



1st prize Case Oral: awarded to Dr F.A. Ashraf (Limerick) by Prof David Kane (ISR President)

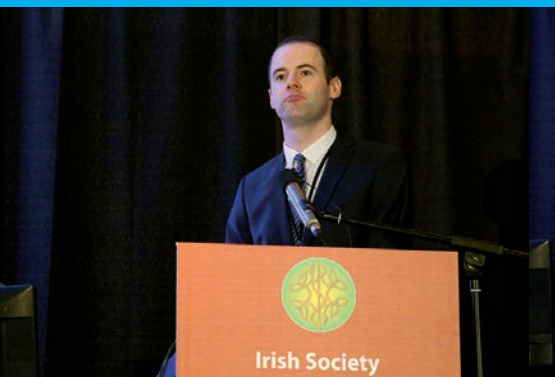


1st prize Poster: Dr Carmel Silke accepting on behalf of Bernie McGowan (Manorhamilton) from Prof David Kane (ISR President)



2nd prize Poster: awarded to Dr Lorraine O'Neill (SVUH) by Prof David Kane (ISR President)

## Oral Cases, Friday 12th September



Dr Aidan O'Neill



Dr F A Ashraf



Dr Carl Orr





PROVEN EVIDENCE ACROSS  
ALL 3 STAGES OF axSpA<sup>1,9</sup>

SIGNIFICANT AND SUSTAINED  
IMPROVEMENTS IN DISEASE  
ACTIVITY AND FUNCTION<sup>1,9</sup>

NOT ASSOCIATED WITH  
NEUTRALISING ANTIBODIES<sup>1</sup>

# THE ENBREL WAY

ACROSS ALL STAGES OF axSpA

axSpA, Axial SpondyloArthritis

\* Enbrel is licensed for the treatment of adults with severe non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated CRP and/or MRI evidence who have had an inadequate response to nonsteroidal anti-inflammatory drugs and for the treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy.<sup>1</sup>

## ABBREVIATED PRESCRIBING INFORMATION

### Enbrel<sup>®</sup> etanercept

Before prescribing Enbrel<sup>®</sup> please refer to full Summary of Product Characteristics (SmPC). **Presentation:** Enbrel Pre-filled Syringe: Enbrel 25 mg and 50 mg solution for injection in pre-filled syringe. Each pre-filled syringe contains either 25 mg or 50 mg etanercept. Enbrel Pre-filled Pen (MYCLIC<sup>®</sup>): Enbrel 50 mg solution for injection in pre-filled pen. Each pre-filled pen contains 50 mg etanercept. Enbrel Powder: Enbrel 25 mg powder and solvent for solution for injection. Each vial contains 25 mg etanercept and each pre-filled syringe contains 1 ml water for injections. Enbrel Paediatric: Enbrel 10 mg powder and solvent for solution for injection for paediatric use. Each vial contains 10 mg etanercept and each pre-filled syringe contains 1 ml water for injections. **Uses:** Adults: Moderate to severe active rheumatoid arthritis (RA), in combination with methotrexate, when response to disease-modifying anti-rheumatic drugs (DMARDs), including methotrexate (unless contraindicated), has been inadequate. Enbrel can be given as monotherapy in the case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Severe, active and progressive RA without prior methotrexate treatment. Enbrel alone or with methotrexate has been shown to reduce the rate of progression of joint damage measured by X-ray and to improve physical function. Patients with moderate to severe plaque psoriasis (PP) who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or PUVA. Active and progressive psoriatic arthritis (PsA) when response to DMARDs has been inadequate. Enbrel has been shown to improve physical function in PsA patients, and to reduce the progression rate of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of PsA. Severe active ankylosing spondylitis (AS) when response to conventional therapy has been inadequate. **Non-radiographic axial spondyloarthritis (nr-axSpA):** Treatment of adults with severe non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to nonsteroidal anti-inflammatory drugs (NSAIDs). **Children aged 2-17 years:** Juvenile idiopathic arthritis (JIA). Polyarthritides (rheumatoid factor positive or negative) and extended oligoarthritis from the age of 2 years when inadequate response to, or intolerant of methotrexate. Psoriatic arthritis from the age of 12 years when inadequate response to, or intolerant of methotrexate. Enthesitis-related arthritis from the age of 12 years when inadequate response to, or intolerant of, conventional therapy. **Children aged 6-17 years:** Chronic severe psoriasis when inadequately controlled by, or intolerant to, other systemic therapies or phototherapy. **Dosage:** By subcutaneous injection. **Adults:** RA – 25 mg twice weekly or 50 mg once weekly PP – 25 mg twice weekly or 50 mg once weekly for up to 24 weeks, or 50 mg twice weekly for up to 12 weeks followed by 25 mg twice weekly or 50 mg once weekly for a further 12 weeks if needed. Continuous therapy may be appropriate for some adult patients. Discontinue if no response after 12 weeks. For re-treatment: 25 mg twice weekly or 50 mg once weekly for up to 24 weeks. **AS, nr-axSpA and PsA –** 25 mg twice weekly or 50 mg once weekly. **Children aged 2-17 years:** JIA – 0.4 mg/kg (maximum per dose 25 mg) twice weekly with an interval of 3 – 4 days or 0.8 mg/kg (maximum per dose 50 mg) once weekly. Discontinuation of treatment should be considered in patients who show no response after 4 months. **Children aged 6-17 years:** Plaque psoriasis in children aged 6-17 years – 0.8 mg/kg (maximum per dose 50 mg) once weekly for up to 24 weeks. Discontinue if no response after 12 weeks. For re-treatment: 0.8 mg/kg (maximum per dose 50 mg) once weekly for up to 24 weeks.

**Contra-indications:** Hypersensitivity to any of the ingredients, sepsis or risk of sepsis, active infections. **Warnings and Precautions:** Enbrel should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of RA, JIA, PsA, AS, PP or Paediatric PP. Patients treated with Enbrel should be given the Patient Alert Card. Use carefully in patients predisposed to, or with history of, infection due to underlying diseases other than RA (e.g. advanced or poorly controlled diabetes) or with history of blood dyscrasias, pre-existing or predisposition to demyelinating disease or congestive heart failure. Cases of active tuberculosis have been reported, therefore all patients should be evaluated for both active and inactive TB prior to being treated with Enbrel. If active TB is diagnosed, Enbrel should not be initiated. Caution should be used when administering Enbrel to patients previously infected with hepatitis B and there have been reports of worsening hepatitis C in patients receiving Enbrel. Use with caution in patients with a history of hepatitis C. Whether treatment with Enbrel might influence the development and course of active and/or chronic infections is unknown. Concurrent administration of Enbrel and anakinra has been associated with increased risk of serious infections and neutropenia, and is therefore not recommended. In clinical studies, concurrent administration of abatacept and Enbrel resulted in increased incidences of serious adverse events, and is therefore not recommended. Use caution when considering combination therapy with DMARDs other than methotrexate. Reports of various malignancies have been received in the post-marketing period, therefore with current knowledge, a possible risk for the development of lymphomas, leukaemia or other haematopoietic or solid malignancies in patients treated with a TNF-antagonist cannot be excluded. Malignancies, some fatal, have been reported among children, adolescents and young adults (up to 22 years of age) treated with TNF-antagonists (initiation of therapy ≤ 18 years of age) in the post-marketing setting. Melanoma and non-melanoma skin cancer (NMSC) have been reported in patients treated with TNF-antagonists, including Enbrel. Post-marketing cases of Merkel cell carcinoma have been reported very infrequently in patients treated with Enbrel. Periodic skin examination is recommended for all patients, particularly those with

risk factors for skin cancer. Enbrel has not been studied in combination with other systemic therapies or phototherapy for the treatment of psoriasis. Monitor closely if patient develops new infection during treatment. Discontinue treatment if serious infection or allergic reaction develops or if blood dyscrasias are confirmed. Caution should be used in patients who have moderate to severe alcoholic hepatitis and Enbrel should not be used in patients for the treatment of alcoholic hepatitis. Discontinue temporarily if significantly exposed to varicella virus. Live vaccines should not be given concurrently with Enbrel. Paediatric patients should have received all vaccines recommended in current immunization guidelines prior to starting Enbrel. Treatment with Enbrel may result in the formation of autoantibodies. Enbrel is not recommended for use in patients with Wegener's granulomatosis. There have been reports of hypoglycaemia in Enbrel patients receiving medication for diabetes, necessitating a reduction in anti-diabetic medication in some of these patients. There have been reports of Inflammatory Bowel Disease (IBD) and uveitis in JIA patients being treated with Enbrel. Caution should be exercised when treating the elderly and with particular attention to occurrence of infections. **Pregnancy & Lactation:** Enbrel is not recommended in pregnant or breast-feeding women. **Undesirable Effects:** Adults: The most commonly reported adverse reactions are injection site reactions, infections, allergic reactions, development of autoantibodies, itching, and fever. See SmPC for less commonly reported side effects. TNF-antagonists, such as Enbrel, affect the immune system and their use may affect the body's defences against infection and cancer. Serious infections affect fewer than 1 in 100 patients treated with Enbrel. Reports have included fatal and life-threatening infections and sepsis. Various malignancies have also been reported with use of Enbrel, including cancers of the breast, lung, skin and lymphatic system (lymphoma). Serious infections and other adverse events such as uncommon reports of: thrombocytopenia, systemic vasculitis, uveitis and scleritis, interstitial lung disease, rare reports of tuberculosis, opportunistic infections, anaemia, leucopenia, neutropenia, pancytopenia, seizures, worsening of heart failure, autoimmune hepatitis, Steven Johnson's syndrome and very rare reports of: anaphylaxis, toxic epidermal necrolysis and aplastic anaemia have been reported. Reactivation of hepatitis B (a liver infection) and worsening of symptoms of dermatomyositis have also been reported. Central and peripheral demyelinating events have been seen rarely and very rarely, respectively, with Enbrel use. There have been rare reports of lupus, lupus-related conditions, and vasculitis. Rate of new malignancies was similar to that expected for the population studied. Fatalities associated with serious infections, pancytopenia, aplastic anaemia and interstitial lung disease have also been reported. **Paediatrics:** Generally as for adults, except the following were more common: headaches, nausea, vomiting and abdominal pain. In addition the following were reported as severe events: varicella, appendicitis, gastroenteritis, depression/ personality disorder, cutaneous ulcer, oesophagitis/gastritis, group A streptococcal septic shock, type I diabetes mellitus and soft tissue and post operative wound infection. There have been post-marketing reports of IBD and uveitis in JIA patients, including cases indicating a positive re-challenge. See section 4.8 of the SmPC for how to report adverse reactions. **Package Quantities:** Enbrel Pre-filled Syringe: Each carton contains 4 pre-filled syringes containing either 25 mg or 50 mg of Enbrel and 4 alcohol swabs. Enbrel Pre-filled Pen (MYCLIC<sup>®</sup>): Each carton contains 4 pre-filled pens containing 50 mg of Enbrel and 4 alcohol swabs. Enbrel Powder: Each carton contains 4 vials of Enbrel 25 mg powder, 4 pre-filled syringes of water for injections, 4 needles, 4 vial adaptors and 8 alcohol swabs. Enbrel Paediatric (10 mg): Each carton contains 4 vials of Enbrel 10 mg powder, 4 pre-filled syringes of water for injections, 4 needles, 4 vial adaptors and 8 alcohol swabs.

**European Marketing Authorisation Numbers:** Enbrel Pre-filled Syringe 25 mg: EU/1/99/126/013 Enbrel Pre-filled Syringe 50 mg: EU/1/99/126/017 Enbrel Pre-filled Pen (MYCLIC<sup>®</sup>) 50 mg: EU/1/99/126/020 Enbrel Powder 25 mg: EU/1/99/126/003 Enbrel Paediatric 10 mg: EU/1/99/126/022. **Legal Category:** S1A. **European Marketing Authorisation Holder:** Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NU, UK. **For full prescribing information see the Summary of Product Characteristics. For further information on this medicine please contact:** Pfizer Medical Information on 1800 633 363 or at EUMEDINFO@pfizer.com. For queries regarding product availability please contact: Pfizer Healthcare Ireland, Pfizer Building 9, Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24 + 353 1 4676500. **API Reference Number:** EN 8\_0. **Pfizer number:** 2013-0003980. **Date of Prescribing Information:** July 2014

### References:

1. Enbrel (etanercept) SmPC. [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/EPAR\\_-\\_Product\\_Information/human/000262/WC500027361.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000262/WC500027361.pdf). Last accessed June 2014.
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3. Maksymowych WP et al. Poster presented at: EULAR Annual Meeting; Paris, France, June 11-14, 2014. Poster FR0260.
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6. Song IH et al. *Ann Rheum Dis*. 2013;72(6):823-825.
7. Pavelka K et al. *Clin Exp Rheum*. 2009;27:964-969.
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9. Dougados M et al. *Ann Rheum Dis*. 2011;70:799-804.





IN DMARD-IR AND TNF-IR RA PATIENTS,  
WHEN COMBINATION WITH MTX IS NOT AN OPTION...

THINK  
ROACTEMRA<sup>1</sup>

Now available in  
Subcutaneous (SC)

**RoACTEMRA<sup>®</sup>**  
tocilizumab

ABRIDGED PRESCRIBING INFORMATION. (For full prescribing information, refer to the Summary of Product Characteristics [SmPC])

RoActemra® (tocilizumab) 20mg/ml Concentrate for Solution for Infusion (RoActemra IV) and RoActemra® 162mg solution for injection in pre-filled syringe (RoActemra SC)

Indications: ABRIDGED PRESCRIBING INFORMATION. (For full prescribing information, refer to the Summary of Product Characteristics [SmPC]). RoActemra® (tocilizumab) 20mg/ml Concentrate for Solution for Infusion (RoActemra IV) and RoActemra® 162mg solution for injection in pre-filled syringe (RoActemra SC)

Indications: **RoActemra SC:** In combination with methotrexate (MTX), for the treatment of adult patients with moderate to severe active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. **RoActemra IV:** In combination with MTX for the treatment of (i) severe, active and progressive RA in adults not previously treated with MTX, (ii) adult patients with moderate to severe active RA who have had an inadequate response or intolerance to one or more DMARDs or TNF antagonists, (iii) active systemic juvenile idiopathic arthritis (sJIA) in patients  $\geq 2$  years of age, who responded inadequately to previous therapy with MTX, RoActemra IV/SC can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate for all indications. RoActemra IV/SC has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with MTX for the treatment of adult RA patients. **Dosage & Administration:** Treatment should be initiated by HCPs experienced in the diagnosis and treatment of RA, sJIA or pJIA and all patients should be given the Patient Alert Card. **RA: RoActemra IV:** 8mg/kg diluted to a final volume of 100ml, given once every 4 weeks by IV infusion over 1 hour. For patients  $>100$ kg, doses  $>800$ mg per infusion are not recommended. No data on doses above 1.2g. **RoActemra SC:** 162mg once every week, irrespective of weight. Patients may self-inject after training. Rotate injection site frequently. **sJIA (RoActemra IV only):** Patients  $<2$  years of age – no data. Patients  $\geq 2$  years, 8mg/kg diluted to final volume of 100ml for patients  $\geq 30$ kg or 12mg/kg diluted to final volume of 50ml for patients  $<30$ kg once every 2 weeks by IV infusion over 1 hour. Clinical improvement generally seen within 6 weeks of starting RoActemra; reconsider continued therapy if no improvement. **pJIA (RoActemra IV only):** Patients  $<2$  years of age – no data. Patients  $>2$  years of age, 8mg/kg diluted to final volume of 100ml for patients  $\geq 30$ kg or 10 mg/kg diluted to final volume of 50ml for patients  $<30$ kg once every 4 weeks by IV infusion over 1 hour. Clinical improvement generally seen within 12 weeks of starting RoActemra; reconsider continued therapy if no improvement. For pJIA/sJIA: check patient's weight at each visit. **Dose adjustments:** For raised liver enzymes, modify concomitant DMARDs if appropriate, reduce or interrupt dose of RoActemra; for low absolute neutrophil count (ANC) or low platelet count reduce or interrupt RoActemra. In some instances discontinue RoActemra (see SmPC). **Special Populations:** No data available for RoActemra SC in patients  $<18$  years of age. Closely monitor renal function in patients with moderate to severe renal impairment. No data in patients with hepatic impairment. No dose adjustments in patients  $>65$  years. **Contraindications:** Hypersensitivity to any component of the product; active, severe infections. **Warnings & Precautions:** Cases of serious infections (sometimes fatal) have been reported; interrupt therapy until controlled. Caution in patients with recurring/chronic infections, or other underlying conditions (e.g. diverticulitis, diabetes and interstitial lung disease) which predisposes to infection. Patients and parents/guardians of sJIA and pJIA patients should contact their HCP when symptoms suggestive of infection appear. Screen for latent TB and treat if required prior to starting therapy. Patients to seek medical attention if sign/symptoms suggestive of TB occur during or after treatment. Viral reactivation (e.g. hepatitis B) reported with biologic therapies. Caution in patients with a history of intestinal ulceration or diverticulitis. Serious hypersensitivity reactions, including anaphylaxis, reported and may be severe and potentially fatal in patients who have experienced hypersensitivity reactions during previous treatment even if they have received premedication with steroids and anti-histamines. If an anaphylactic reaction or other serious hypersensitivity/serious infusion related reaction occurs, permanently discontinue RoActemra. Use with caution in patients with active hepatic disease/impairment. Not recommended in patients with baseline ALT or AST  $> 5 \times$  ULN; caution in patients with ALT or AST  $> 1.5 \times$  ULN (see SmPC). Risk of neutropenia may increase in patients previously treated with TNF antagonist. Continued therapy not recommended in patients with ANC  $< 0.5 \times 10^9/l$  or platelet count  $< 50 \times 10^9/l$ . Do not initiate RoActemra treatment where ANC is below  $2 \times 10^9/l$ . Caution in patients with low platelet count; monitor neutrophils and platelets in RA, sJIA and pJIA patients according to SmPC. Elevations in lipid parameters seen; if elevated, follow local guidelines. Be vigilant for symptoms of new-onset central demyelinating disorders. Immunomodulatory medicines may increase malignancy risk in RA patients. Live and live attenuated vaccines should not be given concurrently (see SmPC). Not recommended for use with other biological agents. Macrophage activation syndrome (MAS), a serious life-threatening disorder, may develop in sJIA patients – RoActemra not studied in patients during an active MAS episode. Trade name should be clearly recorded in patient file to improve traceability of biological medicines. **Drug Interactions:** Studies only performed in adults. Monitor patients taking medicines individually adjusted and metabolised via CYP450 3A4, 1A2 or 2C9 when starting/stopping RoActemra, as doses may need to be increased to maintain therapeutic effect. Effects of tocilizumab on CYP450 enzyme activity may persist for several weeks after stopping therapy (refer to SmPC for further details on cytochrome CYP450 and other drug interactions).

**Fertility, Pregnancy & Lactation:** Women should use contraception during and up to 3 months after treatment. No adequate data from use in pregnant women. Animal study showed increased risk of spontaneous abortion/embryo-fetal death at high dose. RoActemra should not be used during pregnancy unless clearly necessary. No lactation data in humans. A decision on whether to continue/discontinue breastfeeding or RoActemra therapy should be made taking into account the relative benefits to the child and mother. Refer to SmPC. **Effects on ability to drive and use machines:** RoActemra has minor influence on the ability to drive and use machines (dizziness). **Undesirable Effects:** Prescribers should consult SmPC for full details of ADRs. **RoActemra IV:** RA: ADRs occurring in RoActemra trials: Very Common ( $\geq 1/10$ ): upper respiratory tract infections, hypercholesterolaemia. Common ( $\geq 1/100 - <1/10$ ): cellulitis, pneumonia, oral herpes simplex, herpes zoster, abdominal pain, mouth ulceration, gastritis, rash, pruritus, urticaria, headache, dizziness, hepatic transaminases increased, weight increased, total bilirubin increased, hypertension, leucopenia, neutropenia, peripheral oedema, hypersensitivity reactions, conjunctivitis, cough and dyspnoea. **sJIA:** ADRs were similar to those seen in RA patients. Serious infections of varicella and otitis media reported (in addition to infections for RA). Hypersensitivity reactions requiring treatment discontinuation occurred in  $<1\%$  of patients. Other events occurring within 24 hours of infusion (16% of patients) included rash, urticaria (considered serious), diarrhoea, epigastric discomfort, arthralgia and headache. Decreased IgG levels during therapy. **pJIA:** ADRs were similar to those seen in RA and sJIA patients. Nasopharyngitis, headache, nausea, and decreased neutrophil count more frequently reported in the pJIA population. The incidence of infections leading to dose interruptions was numerically higher in patients weighing  $<30$ kg, the rate of serious infections was also higher in these patients. 20.2% experienced an infusion reaction within 24 hours of infusion. **RoActemra SC:** The safety and immunogenicity was consistent with the known safety profile of IV. Injection site reactions (including erythema, pruritus, pain and haematoma) were mild to moderate in severity. **Serious or Potentially Serious:** serious infections, active tuberculosis, invasive pulmonary infections, interstitial lung disease (including pneumonitis and pulmonary fibrosis), GI perforations (as complications of diverticulitis), serious hypersensitivity reactions, Stevens-Johnson syndrome. See SmPC section 4.8 for instructions on the reporting of Suspected Adverse Reactions. **Legal Category:** Subject to medical prescription which may not be renewed (A). **Presentations & Marketing Authorisation Numbers:** 80mg of tocilizumab in 4ml (20mg/ml) pack of 1 (EU/1/08/492/001); 200mg of tocilizumab in 10ml (20mg/ml) pack of 1 (EU/1/08/492/003); 400mg of tocilizumab in 20ml (20mg/ml) pack of 1 (EU/1/08/492/005); 162mg tocilizumab solution for injection (in 0.9ml) in pre-filled syringe (EU/1/08/492/007).

**Marketing Authorisation Holder:** Roche Registration Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom. RoActemra is a registered trade mark. Further information is available from Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24. Telephone: (01) 4690700. Fax: (01) 4690791. **Date of Preparation:** March 2015.

**References:** 1. Nisar MK et al. The role of tocilizumab monotherapy in the management of rheumatoid arthritis: a review. Int. J. Clin. Rheumatol. (2012) 7(1): 9-19.

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