



Embargoed until 00:01 Thursday, 21 January

NICE Approves New Rheumatoid Arthritis (RA) Treatment Cimzia® (certolizumab pegol) With First Of Its Kind RA Patient Access Scheme

First RA treatment to be approved by NICE in more than two years¹

Slough, UK, EMBARGOED UNTIL 00:01 Thursday 21 January 2010 – A new drug will be available on the NHS from today for adults with severe active rheumatoid arthritis (RA).

The drug, Cimzia® (certolizumab pegol), has received a positive appraisal from NICE² and is recommended as an option for the treatment of adults with severe active RA on the condition that the Patient Access Scheme is implemented and the drug is prescribed in accordance with NICE TAG130³.

The registered UK indication for the drug Cimzia is for use in combination with methotrexate (MTX), 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. Cimzia can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.⁴

In England an estimated 580,000 adults suffer with RA⁵. RA is a debilitating, chronic disease which causes joint inflammation and which can lead to long-term joint damage, resulting in pain, disability and disfigurement⁶. Women are two to three times more likely to suffer from RA than men⁷ and the disease strikes people in the prime of their lives between the ages of 30-50⁷.

In a novel move for drugs in RA, manufacturer UCB has worked with the Department of Health to provide a clear, cost effective alternative for people with RA through a Patient Access Scheme. In clinical studies, the new drug has demonstrated rapid treatment efficacy with significant results as early as the first week of treatment^{8,9}, and the majority of patients responded to treatment within the first 12 weeks^{8,9}. As such, UCB and the Department of Health have agreed a patient access scheme to ensure that treatment decisions are based on patient need rather than cost^{10,2}. UCB will make the newly approved NICE treatment available to all eligible RA patients free of charge for the first 12 weeks¹⁰. This means no cost to the NHS for patients prescribed the drug for the first 12 weeks of treatment regardless of whether they respond to treatment or not¹⁰.

Ailsa Bosworth, Chief Executive of the National Rheumatoid Arthritis Society, comments: "This is the first time a new RA treatment has been approved by NICE in over two years - and could make a big difference to patients' day to day lives."

Clinical trials have also shown that, the drug, in combination with methotrexate – the treatment most often prescribed for RA – has shown fast and lasting RA symptom reduction for up to two years¹¹. These sustained results were accompanied by long-term



improvements to quality of life such as pain relief, fatigue, energy and emotional well-being^{11,12}.

“Certolizumab pegol is an important new treatment option for people with rheumatoid arthritis, and it’s exciting that it is now available on the NHS ,” commented Professor Peter Taylor, investigator and Professor in Experimental Rheumatology, Imperial College London NHS Trust. “Certolizumab pegol has been shown to rapidly improve patients’ symptoms and to significantly reduce the rate of progression of joint damage associated with rheumatoid arthritis*. This fast and lasting effect is important as it quickly improves function, reduces work disability and leads to a better quality of life for patients⁸.”

The new treatment is available in an innovative pre-filled syringe⁴, and its award winning [Red Dot] packaging¹³ has been designed with the U.S. consumer products company OXO, maker of Good Grips[®], in consultation with RA patients, taking into account the challenges faced when self-injecting medication, as painful or inflamed joints can limit dexterity.

*compared to placebo plus MTX treatment in RA patients with an incomplete response to MTX in clinical trials.

For full prescribing information visit

<http://www.emea.europa.eu/humandocs/PDFs/EPAR/cimzia/emea-combined-h1037en.pdf>.

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Notes to the editor

About Cimzia[®] (certolizumab pegol)

Certolizumab pegol is the first PEGylated anti-TNF (Tumour Necrosis Factor alpha) to be launched in England and Wales for the treatment of moderate to severe active RA, in combination with methotrexate (MTX), in adult patients when the response to disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate, has been inadequate (for full indication see SPC)⁴. Certolizumab pegol has also been approved for use alone as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate, in the same patient population⁴. Certolizumab pegol is a monoclonal antibody with high specificity for human TNF-alpha, selectively neutralising the



pathophysiological effects of TNF-alpha⁴. Over the past decade, TNF-alpha has emerged as a major target of basic research and clinical investigation. This cytokine plays a key role in mediating inflammation, and excess TNF-alpha production has been directly implicated in a wide variety of diseases. The launch of certolizumab pegol follows marketing authorisation on 5 October, 2009 by the European Medicines Agency (EMA). Cimzia[®] is a registered trademark of UCB PHARMA S.A.

Important safety information

The most common adverse reactions belonged to the system organ classes Infections and infestations, reported in 15.5% of patients on Cimzia[®] and 7.6% of patients on placebo, and General disorders and administration site conditions, reported in 10.0% of patients on Cimzia[®] and 9.7% of patients on placebo. The most serious adverse reactions were serious infections (including tuberculosis and histoplasmosis), malignancies (including lymphoma) and heart failure. A pooled analysis of the safety data show there was a low incidence of injection site pain (1.5 percent) and low level of discontinuations due to adverse events.

Cimzia[®] is contraindicated in patients with active tuberculosis or other severe infections such as sepsis, abscesses and opportunistic infections and in patients with moderate to severe heart failure. Before initiation of Cimzia[®], evaluate patients for both active or inactive (latent) tuberculosis infection. Monitor patients for the development of signs and symptoms of infection during and after treatment with Cimzia[®]. If an infection develops, monitor carefully, and stop Cimzia[®] if infection becomes serious.

Use of TNF blockers, including Cimzia[®], may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers of this virus, of new onset or exacerbation of clinical symptoms and/or radiographic evidence of demyelinating disease, in the formation of autoantibodies and uncommonly in the development of a lupus-like syndrome or of severe hypersensitivity reactions following Cimzia administration. If a patient develops any of these adverse reactions, Cimzia[®] should be discontinued and appropriate therapy instituted.

Adverse reactions of the hematologic system, including medically significant cytopenia, have been infrequently reported with Cimzia[®]. Advise all patients to seek immediate medical attention if they develop signs and symptoms suggestive of blood dyscrasias or infection (e.g., persistent fever, bruising, bleeding, pallor) while on Cimzia[®]. Consider discontinuation of Cimzia[®] therapy in patients with confirmed significant haematological abnormalities.

The use of Cimzia[®] in combination with biological DMARDs such as anakinra, abatacept and rituximab is not recommended due to a potential increased risk of serious infections. As no data are available, Cimzia[®] should not be administered concurrently with live vaccines or attenuated vaccines.

Please see full prescribing information before prescribing.

About the NICE FAD

The National Institute of Health and Clinical Excellence (NICE) has today published a positive Final Appraisal Determination (FAD) for certolizumab pegol, recommending its use across England and Wales, following a Single Technology Appraisal (STA) process which reviewed its cost-effectiveness in the management of RA. Certolizumab pegol is



recommended as an option for the treatment of adults with severe active RA on the condition that the PAS is implemented and the drug is prescribed in accordance with NICE TAG130^{2,3}.

The Secretary of State and the Welsh Assembly Minister for Health and Social Services have issued directions to the NHS on implementing NICE technology appraisal guidance. When a NICE technology appraisal recommends use of a drug or treatment, or other technology, the NHS must provide funding and resources for it within 3 months of the guidance being published. If the Department of Health issues a variation to the 3-month funding direction, details will be available on the NICE website. Further information on the NICE guidance can be found at www.nice.org.uk.

About UCB

UCB, Brussels, Belgium is a biopharmaceutical company dedicated to the research, development and commercialisation of innovative medicines with a focus on the fields of central nervous system and immunology disorders. Employing approximately 10,000 people in over 40 countries, UCB generated revenue of EUR 3.6 billion in 2008. UCB is listed on Euronext Brussels (symbol: UCB).

Forward-looking statements

This press release contains forward-looking statements based on current plans, estimates and beliefs of management. Such statements are subject to risks and uncertainties that may cause actual results to be materially different from those that may be implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: changes in general economic, business and competitive conditions, effects of future judicial decisions, changes in regulation, exchange rate fluctuations and hiring and retention of its employees.

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