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

- **Cimzia®**, the first PEGylated anti-TNF, receives recommendation for approval from NICE for the treatment of severe, active RA in adults

- **Under the Patient Access Scheme the new drug will be available free of charge to every eligible NHS RA patient in England and Wales for the first 12 weeks of therapy**

- **UCB partners with U.S. consumer products company OXO, makers of Good Grips®, to produce a new prefilled syringe, designed to overcome challenges many people with RA face when self-injecting**

**Slough, UK, Thursday 21 Jan 2010** – UCB announced today that the National Institute for Health and Clinical Excellence (NICE) has issued a recommendation for approval to the NHS for the use of Cimzia®, certolizumab pegol 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 TAG130².

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.⁷

The NICE guidance also mentions a first of its kind Patient Access Scheme in RA, which will make certolizumab pegol available free of charge to all eligible NHS patients for the first 12 weeks of therapy,³ at which point clinical response is usually achieved.

RA is a debilitating, chronic disease which causes joint inflammation and which can lead to long-term joint damage, resulting in pain, disability and disfigurement⁴. Women are two to three times more likely to suffer from RA than men⁵ and the disease strikes people in the prime of their lives between the ages of 30-50⁵. There are an estimated 580,000 adults living with RA in England alone.⁶

Ailsa Bosworth, Chief Executive of the National Rheumatoid Arthritis Society, comments: “This is the first time a new NICE recommended RA treatment has been made available for almost two years - and could make a big difference to patients’ day to day lives.”

Certolizumab pegol is the first PEGylated anti-TNF (Tumour Necrosis Factor alpha) to be launched in the U.K. for the treatment of moderate to severe active RA (recommended for approval by NICE for the treatment of severe active RA in England and Wales), in combination with methotrexate (MTX), in adult patients when the response to disease-modifying anti-rheumatic drugs (DMARDs) including MTX, has been inadequate (for full indication see SPC⁷). In clinical trials with certolizumab pegol together with MTX, significant improvement in ACR⁴ scores (20, 50 and 70) was evident at Week 1. These improvements continued rapidly over the first 4–12 weeks of treatment and remained significant relative to the placebo treatment group at Weeks 24 and 52.⁸
“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 patients”.

UCB has also teamed up with the U.S. consumer products company OXO, maker of Good Grips®, to design a new syringe and packaging components for certolizumab pegol that take into account the challenges many people with RA face when self-injecting, since painful or inflamed joints can limit their dexterity. The new prefilled syringe was designed with the help of RA patients for use by patients with different grip styles and strengths.

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

ACR (American College of Rheumatology) response scores measure improvement in the tender and swollen joint count and also include assessment of the following five parameters: patient’s global assessment, physician’s global assessment, patient’s assessment of pain, degree of disability, and level of acute-phase reactant. ACR20 is achieved when there is 20% improvement in the tender and swollen joint count as well as a 20% improvement in at least three of the five parameters. ACR50 and ACR70 are an extension of these criteria corresponding to a 50% and 70% improvement respectively.


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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 the U.K. for the treatment of moderate to severe active RA (recommended for approval by NICE for the treatment of severe active RA in England and Wales) in combination with MTX, in adult patients when the response to disease-modifying anti-rheumatic drugs (DMARDs) including MTX, has been inadequate (for full indication see SPC*). 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 population. Certolizumab pegol is a monoclonal antibody with high specificity for
human TNF-alpha, selectively neutralising the pathophysiological effects of TNF-alpha. 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 (EMEA). 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 draft Final Appraisal Determination (FAD) for certolizumab pegol, recommending it for approval for 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 for approval 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.$^1,^2$

**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.

**References**
1. NICE. Final Appraisal Determination for certolizumab pegol for the treatment of rheumatoid arthritis
2. NICE TA130 – Rheumatoid Arthritis guidance http://www.nice.org.uk/TA130