Cimzia®, the only PEGylated anti-TNF, recommended for approval in the EU for rheumatoid arthritis

Brussels (Belgium), June 26, 2009 – Press Release, regulated information - UCB announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMEA) has issued a positive opinion recommending that the European Commission grants a marketing authorisation for Cimzia® (*certolizumab pegol*), in combination with methotrexate (MTX), for the treatment of moderate to severe active rheumatoid arthritis in adult patients when the response to disease-modifying anti-rheumatic drugs (DMARDs) including MTX, has been inadequate. In these patients, 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.

The recommendation has been granted for Cimzia® to be administered as a subcutaneous injection using the pre-filled syringe.

“The CHMP positive opinion is a significant milestone for UCB, but especially for people suffering from rheumatoid arthritis,” said Roch Doliveux, Chief Executive Officer of UCB. “Cimzia® can provide an additional effective treatment option for patients with this debilitating condition, helping them to lead fuller lives.”

The European Commission usually delivers a European marketing authorisation subsequent to a positive CHMP opinion within three months. Following European marketing authorisation the first launches of Cimzia®, in the European Union, are anticipated before the end of 2009.

The CHMP decision is supported by data from a comprehensive clinical development programme, involving more than 2 300 patients with RA and over 4 000 patient-years experience.

In the pivotal clinical trials, reported serious adverse reactions, as with other anti-TNF's, included infections (including tuberculosis) and malignancies (including lymphoma), and the most commonly occurring adverse events were upper respiratory tract infections, rash and urinary tract infections. A pooled analysis of the safety data showed a low incidence of injection site pain (1.5%) and a low level of discontinuations due to adverse events (5%). Cimzia® demonstrated a favorable risk-benefit profile in patients with at least up to two years of drug exposure.

On 14 May, the U.S. Food and Drug Administration (FDA) approved Cimzia® for the treatment of adult patients with moderately to severely active rheumatoid arthritis.

For further information

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Notes to the editor

About Cimzia®

Cimzia® is the only PEGylated anti-TNF (Tumor Necrosis Factor). Cimzia® has a high affinity 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 pathological inflammation, and excess TNF-alpha production has been directly implicated in a wide variety of diseases.
The U.S. Food and Drug Administration (FDA) has approved Cimzia® for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderate to severe active disease who have had an inadequate response to conventional therapy and for the treatment of adults with moderate to severely active rheumatoid arthritis.
Cimzia® was approved in Switzerland in September 2007 for induction of a clinical response and for the maintenance of a clinical response and a remission in patients with active Crohn's disease who have not responded adequately to conventional treatment. UCB is also developing Cimzia® in other autoimmune disease indications. Cimzia® is a registered trademark of UCB PHARMA S.A.
Reported serious adverse reactions of Cimzia® were infections (including tuberculosis and histoplasmosis) and malignancies including lymphoma. The most commonly occurring adverse events were upper respiratory tract infections, rash and urinary tract infections. A pooled analysis of the safety data show there was a low incidence of injection site pain (1.5%) and a low level of discontinuations due to adverse events (5%).

About UCB

UCB, Brussels, Belgium (www.ucb.com) 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.