

## UCB to conduct first anti-TNF head-to-head study between Cimzia® (certolizumab pegol) and Humira®\* (adalimumab)

- First blinded and randomised study comparing effectiveness of two anti-TNF agents for the treatment of rheumatoid arthritis
- Study to evaluate the relative clinical and treatment outcomes of the two anti-TNF agents based upon clinical response at Week 12

**BRUSSELS, 25 May 07:00 (CET)** – UCB today announced its plan to launch the first industry sponsored anti-TNF head-to-head study that will assess the effectiveness of Cimzia® (certolizumab pegol) and Humira® (adalimumab) in the treatment of moderate to severe rheumatoid arthritis (RA). The study will include a week 12 response-based therapeutic decision and assess the impact of an early response and decision on long-term (104 weeks) clinical and patient outcomes. The EULAR 2010 Recommendations and those from an International task force, The Treat-to-Target Expert Committee, state that appropriate therapeutic adaptation to reach treatment targets of remission or low disease activity should be made to reach the desired state within 3 to a maximum of 6 months.<sup>1,2</sup>

“We are delighted to announce our plan to launch this head-to-head study. We believe the study will provide additional evidence that the ability to make an informed and early treatment decision is important for the treatment of this severe and progressing disease,” said Professor Dr Iris Loew-Friedrich, Chief Medical Officer of UCB, Belgium.

Persistent active disease is a predisposing factor of subsequent disease severity, such as progressive joint damage, irreversible disability and increased mortality<sup>3-6</sup>. Therefore, stopping inflammation rapidly can be an important therapeutic goal and several studies have shown that achieving control of disease activity, ideally rapid control, has led to improved long term outcomes for patients with RA.<sup>7,8</sup>

The study will randomise patients to either certolizumab pegol plus methotrexate (MTX) or adalimumab plus MTX for 12 weeks, after which patients who respond will continue on their treatment whereas non-responders will switch to the alternative treatment arm until study end at 104 weeks. The worldwide study aims to recruit patients with moderate-to-severe RA who have inadequately responded to MTX and who have not previously received anti-TNF treatment.

*\* Humira® is a registered trademark of Abbott*



**For further Information:**

Antje Witte, Investor Relations, UCB

T +32.2.559.9414, [antje.witte@ucb.com](mailto:antje.witte@ucb.com)

Michael Tuck-Sherman, Investor Relations, UCB

T +32.2.559.9712, [Michael.tuck-sherman@ucb.com](mailto:Michael.tuck-sherman@ucb.com)

Nancy Nackaerts, External Communications, UCB

T +3235599264, [nancy.nackaerts@ucb.com](mailto:nancy.nackaerts@ucb.com)

**Cimzia® (certolizumab pegol) in European Union/ EEA important safety information**

Cimzia® was studied in 2367 patients with RA in controlled and open label trials for up to 57 months. The commonly reported adverse reactions (1-10%) in clinical trials with Cimzia® and post-marketing were viral infections (includes herpes, papillomavirus, influenza), bacterial infections (including abscess), rash, headache (including migraine), asthenia, leukopaenia (including lymphopaenia, neutropaenia), eosinophilic disorder, pain (any sites), pyrexia, sensory abnormalities, hypertension, pruritis (any sites), hepatitis (including hepatic enzyme increase), injection site reactions. Serious adverse reactions include sepsis, opportunistic infections, tuberculosis, herpes zoster, lymphoma, leukaemia, solid organ tumours, angioneurotic edema, cardiomyopathies (includes heart failure), ischemic coronary artery disorders, pancytopenia, hypercoagulation (including thrombophlebitis, pulmonary embolism), cerebrovascular accident, vasculitis, hepatitis/hepatopathy (includes cirrhosis), and renal impairment/nephropathy (includes nephritis). In RA controlled clinical trials, 5% of patients discontinued taking Cimzia® due to adverse events vs. 2.5% for placebo.

Cimzia® is contraindicated in patients with hypersensitivity to the active substance or any of the excipients, active tuberculosis or other severe infections such as sepsis or opportunistic infections, 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.

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

With the current knowledge, a possible risk for the development of lymphomas, leukaemia or other malignancies in patients treated with a TNF antagonist cannot be excluded. Rare cases of neurological disorders, including seizure disorder, neuritis and peripheral neuropathy, have been reported in patients treated with Cimzia®.

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 anakinra or abatacept 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. The 14-day half-life of Cimzia® should be taken into consideration if a surgical procedure is planned. A patient who requires surgery while on Cimzia® should be closely monitored for infections.

Please consult the full prescribing information in relation to other side effects, full safety and prescribing information. European SmPC date of revision February 2011.

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/EPAR\\_-\\_Product\\_Information/human/001037/WC500069763.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001037/WC500069763.pdf)



### **About CIMZIA®**

*Cimzia® is the only PEGylated anti-TNF (Tumor Necrosis Factor). Cimzia® has a high affinity for human TNF-alpha, selectively neutralizing 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 moderately to severely active disease who have had an inadequate response to conventional therapy and for the treatment of adults with moderately to severely active rheumatoid arthritis. Cimzia® in combination with MTX, is approved in the EU for the treatment of moderate to severe active RA in adult patients inadequately responsive to disease-modifying antirheumatic drugs (DMARDs) including MTX. Cimzia® can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate. UCB is also developing Cimzia® in other autoimmune disease indications. Cimzia® is a registered trademark of UCB PHARMA S.A.*

### **About UCB**

*UCB, Brussels, Belgium ([www.ucb.com](http://www.ucb.com)) is a biopharmaceutical company dedicated to the research, development and commercialization of innovative medicines with a focus on the fields of central nervous system and immunology disorders. Employing more than 9000 people in over 40 countries, UCB produced revenue of EUR 3.22 billion in 2010. 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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