



Two-year Cimzia® (certolizumab pegol) data from study showed sustained improvements in household productivity and increased participation in social activities for rheumatoid arthritis patients

- **Treatment with Cimzia® monotherapy* was associated with increased productivity inside the home and increased participation in family, social and leisure activities¹**
- **Improvements in productivity and increased participation in social activities were reported rapidly, as early as week 4, and sustained through 2 years of monotherapy treatment¹**

ROME June 16th, 2010, 08.30 CET — UCB today announced new data presented at the European League Against Rheumatism (EULAR) annual congress in Rome showing that Cimzia®, the only approved PEGylated anti-TNF, provided rapid and sustained improvements in household productivity and increased participation in social activities for adult patients living with active rheumatoid arthritis (RA).¹

“The target of RA treatment is to provide rapid and sustained relief from disease pain and symptoms thus enabling patients to perform household, social, leisure and family activities, the things that are really important,” said Dr Vibeke Strand, Adjunct Clinical Professor in the Division of Immunology and Rheumatology, at Stanford University, California, and lead author. “Observations, such as those made in this study with certolizumab pegol, suggest that efficacious treatments can significantly improve productivity and improve the quality of life for patients.”

Patients in FAST4WARD™ were randomised to Cimzia® 400 mg every 4 weeks or placebo for 24 weeks.* Those who completed or withdrew on/after Week 12 were eligible to enter an open-label extension (OLE) study of Cimzia® 400 mg every 4 weeks as per protocol.* This analysis focuses on Cimzia® completers who entered the OLE study and had 2 years (100 weeks) of Cimzia® exposure from baseline.

The Work Productivity Survey (WPS-RA) used in the study, is a validated questionnaire that evaluated a variety of measures including household productivity – assessed as missed days of household work, days with reduced household productivity and rate of RA impact on household work productivity – as well as the number of missed days of family, social and leisure activities.¹

The WPS-RA was assessed every four weeks starting at baseline for the first 6 months and every 3 months thereafter, with analyses conducted on observed data from the FAST4WARD™ phase III trial open label extension study (FAST4WARD™ OLE).¹ Eligibility criteria for the open label extension included participation in the FAST4WARD™ study for



at least 12 weeks of blinded treatment, without being withdrawn for a possible drug related adverse event or non-compliance.¹

Following Cimzia® monotherapy treatment, patients reported a rapid improvement in productivity within the home.¹ By Week 4, patients reported a lower rate of RA interference with household productivity than at baseline (3.7 rate compared with 5.8 rate, on a 0–10 scale where 0=no interference and 10=complete interference).¹ These improvements were sustained and by week 100, only 1 household work day (on average) was missed and only 1.1 household work day with reduced productivity was reported, per month.¹

These improvements in productivity within the home were seen in the majority of patients.¹ In fact, by week 100, about 60% of patients did not miss any day of household work and about 90% of patients reported ≤4 missed days of household work per month.¹

Patients treated with Cimzia® monotherapy also reported rapid and sustained improvements in participation in family, social, and leisure activities.¹ By Week 4, Cimzia®-treated patients missed on average fewer days per month of family, social, or leisure activities than at baseline (1.5 days compared with 5.0 days).¹ By Week 100, on average 0.3 days of family, social, or leisure activities were missed, per month.¹ At Week 100, over 80% of patients did not miss any days of family, social, or leisure activities, per month, and all patients reported ≤ 4 days of family, social, or leisure activities, missed per month.¹

The monthly improvements in household productivity reported by Cimzia® patients resulted into annualized cumulative gains, with average incremental gains over baseline of:

- 108 full days of household work by 1 year and 199 by 2 years¹
- 136 more productive days of household work by 1 year and 245 by 2 years¹
- 58 days of social, family, or leisure activities by 1 year and 107 by 2 years¹

In Cimzia®'s pivotal clinical trials reported serious adverse reactions included infections (including tuberculosis) and malignancies (including lymphoma). 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. A pooled analysis of the safety data showed there was 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.

** 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. Cimzia® can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. The recommended starting dose of Cimzia® for adult patients with rheumatoid arthritis is 400 mg (as 2 injections of 200 mg each on one day) at weeks 0, 2 and 4, followed by a maintenance dose of 200 mg every 2 weeks. MTX should be continued during treatment with Cimzia® where appropriate.*



For further information

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Important safety information

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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. This can be accessed at:
www.ema.europa.eu/humandocs/PDFs/EPAR/cimzia/emea-combined-h1037en.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) 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 3.1 billion in 2009. 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.

Reference

1. Strand V, Purcaru O, van Vollenhoven R, Choy E, Fleischmann R. Certolizumab pegol monotherapy provides sustained improvements in household productivity and daily activities in patients with active rheumatoid arthritis over two years. Poster presented at the EULAR Annual European Congress of Rheumatology; 2010, 16-19 June; Rome, Italy.