UCB reinforces its commitment to the arthritis community and saves NHS £10 million through its Patient Access Scheme

- At a time when the NHS is facing cost savings of around £20 billion by 2015, it’s hoped that this £10 million savings will mean less pressure on front-line services

- A £10 million saving could pay for over 1,900 hip replacements (each at £5,227)

**Slough, UK, 17 October 2012:** UCB announced that it has saved the NHS £10 million in costs towards treatment for rheumatoid arthritis (RA) across Northern Ireland, England, Wales and Scotland*. The savings are the result of a Patient Access Scheme (PAS), introduced by UCB in 2010 following the launch of Cimzia® (certolizumab pegol), in which patients receive the first 10 syringes (12 weeks) of treatment for free.

Philip Aubrey, LPP Medicines Use Procurement Productivity Operational Lead stated: “UCB has ensured the PAS is simple to implement and this has been a key to their success. These £10 million savings are a good example of industry and the NHS working together.”

UCB has offered an innovative solution through the PAS. Not only is the scheme helping to improve access to biologic treatments for people living with RA, it is potentially saving the NHS £2,363 of direct costs per patient in comparison to etanercept or adalimumab.

Dr Catherine Ludwig, Medical Director, Immunology at UCB said that “Savings made through the patient access scheme come at an important time for the NHS as it is faced with a need to make cost savings. This £10 million could pay for nearly 2,000 hip replacements. With over 76,000 people receiving new hips every year across England and Wales, this could be a worthwhile re-investment”.

A concern around the use of current anti-TNF treatments is their financial impact on the NHS, particularly when an estimated 20-35% of patients prescribed anti-TNF therapies, fail to respond to treatment.

The advantages of the PAS is that it is in line with certolizumab pegol’s clinical data which enables the prescribing clinician to make a decision, on whether patients are likely to respond to treatment with this therapy after 12 weeks.

In practice this means that clinicians can judge a response rate with certolizumab pegol by the end of the PAS, without any financial risk to the NHS. Only after this 12-week stage will the NHS be charged for continued use of this therapy. The PAS also helps to ensure that treatment with certolizumab pegol is based on clinical need rather than considerations of cost or the financial risk of a failed initial intervention.

The PAS has so far included 4,500 patients eligible for treatment with certolizumab pegol.

*The financial structure of the scheme implemented in Scotland differs to that of England, Wales and Northern Ireland.

In clinical trials 87% of patients treated with certolizumab pegol who achieve a moderate/good response within a year did so by 12 weeks. Only 2% of non-responsive patients in 12 weeks went on to achieve optimal outcomes with certolizumab pegol by the end of their first year of treatment.
About Rheumatoid Arthritis
RA currently affects 580,000 people in the UK. The disease can often be severe for patients; leading to disability and potential unemployment. It is estimated that the UK spends £8 billion each year in work productivity losses as a result of people unable to work due to RA.

About CIMZIA®
Certolizumab pegol is the first PEGylated anti-TNF (Tumour Necrosis Factor alpha) to be launched for the treatment of moderate to severe active RA, in combination with methotrexate (MTX), in adult patients when the response to disease-modifying antirheumatic drugs (DMARDs) including methotrexate, has been inadequate. 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. CIMZIA® is a registered trademark of UCB PHARMA S.A.

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, leukaemia (including lymphopaenia, neutropaenia), eosinophilic disorder, pain (any sites), pyrexia, sensory abnormalities, hypertension, pruritis (any sites), hepatitis (including hepatic enzyme increase) and 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 or moderate to severe heart failure.

Serious infections including sepsis, tuberculosis and opportunistic infections have been reported in patients receiving Cimzia®. Some of these events have been fatal. Monitor patients closely for signs and symptoms of infections including tuberculosis before, during and after treatment with Cimzia®. Treatment with Cimzia must not be initiated in patients with a clinically important active infection. If an infection develops, monitor carefully and stop Cimzia® if infection becomes serious. Before initiation of therapy with Cimzia®, all patients must be evaluated for both active and inactive (latent) tuberculosis infection. If active tuberculosis is diagnosed prior to or during treatment, Cimzia® therapy must not be initiated and must be discontinued. If latent tuberculosis is diagnosed, appropriate anti-tuberculosis therapy must be started before initiating treatment with Cimzia®. Patients should be instructed to seek medical advice if signs/symptoms (e.g. persistent cough, wasting/weight loss, low grade fever, listlessness) suggestive of tuberculosis occur during or after therapy with Cimzia®.

Reactivation of hepatitis B has occurred in patients receiving a TNF-antagonist including Cimzia® who are chronic carriers of the virus (i.e. surface antigen positive). Some cases have had a fatal outcome. Patients should be tested for HBV infection before initiating treatment with Cimzia®. Carriers of HBV who require treatment with Cimzia® should be closely monitored and in the case of HBV reactivation Cimzia® should be stopped and effective anti-viral therapy with appropriate supportive treatment should be initiated.

TNF antagonists including Cimzia® may increase the risk 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 July 2012.


References

1. Department of Health. 2011-12 Best Practice Tariffs
2. UCB data on file
4. Strand V, Coteur G, Ionescu L. Certolizumab pegol demonstrates response as early as week 1 in moderate-severe RA patients. Poster presented at: British Society for Rheumatology Annual Conference; April 28-May 01 2009; Glasgow, UK.
6. Data on file. UCB,Inc; Smyrna GA.
7. National Rheumatoid Arthritis Society

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About UCB

UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With more than 8,000 people in about 40 countries, the company generated revenue of EUR 3.2 billion in 2011. 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. All statements, other than statements of historical fact, are statements that
could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, political, regulatory or clinical results and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions which could cause actual results to differ materially 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, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, product liability claims, challenges to patent protection for products or product candidates, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws and hiring and retention of its employees. UCB is providing this information as of the date of this press release and expressly disclaims any duty to update any information contained in this press release, either to confirm the actual results or to report a change in its expectations.

There is no guarantee that new product candidates in the pipeline will progress to product approval or that new indications for existing products will be developed and approved. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to differences between the partners. Also, UCB or others could discover safety, side effects or manufacturing problems with its products after they are marketed.

Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement.