UCB News

UCB receives CHMP positive opinion for Cimzia® (certolizumab pegol) in active psoriatic arthritis

- CHMP adopts positive opinion for certolizumab pegol in adults with active psoriatic arthritis
- Positive opinion is supported by data from the RAPID™-PsA study
- European Commission decision expected within two months
- Approval would represent the third indication for Cimzia® in the European Union

BRUSSELS (BELGIUM), 25th October 2013 – (15:30 CEST) – UCB today announced that the European Medicines Agency's (EMA's) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending extending the European Union marketing authorization for the use of Cimzia® (certolizumab pegol) in the treatment of adult patients with active psoriatic arthritis (PsA).

PsA is a chronic, inflammatory condition that causes pain, swelling and stiffness in and around the joints and tendons and usually occurs in combination with psoriasis. In most people with PsA, psoriasis develops before joint problems. When hands and feet are affected in PsA, nail changes can occur as well as swelling in the fingers and toes (dactylitis). PsA affects an estimated 24 in 10,000 people and affects up to 30% of psoriasis patients. It usually occurs between the ages of 30 and 50.[1] The long-term burden of PsA is substantial with over half of patients developing progressive, erosive disease with functional impairment.[2]

"This CHMP positive opinion for Cimzia® in active PsA closely follows the European approval of Cimzia® for the treatment of adults with severe active axial spondyloarthritis and illustrates our commitment to the wider population of people in Europe with rheumatic conditions who need innovative, new treatment options," said Professor Dr. Iris Loew-Friedrich, Chief Medical Officer and Executive Vice President UCB. "Results from the RAPID™-PsA study supporting the positive opinion showed that treatment with Cimzia® improved the clinical signs and symptoms of PsA, including arthritis, enthesitis, dactylitis and skin involvement, with a rapid onset of action."

The CHMP recommendation forms the basis for a European Commission licensing decision, which is expected in approximately two months. The positive opinion follows the EMA's review of data from the RAPID™-PsA study, an on-going, Phase 3, multicenter, randomized, double-blind, placebo-controlled trial designed to evaluate the efficacy and safety of certolizumab pegol in patients with adult onset active and progressive PsA.[2]

In the European Union, Cimzia® is approved in combination with methotrexate (MTX) for the treatment of moderate to severe active rheumatoid arthritis in adult patients inadequately responsive to disease-modifying anti-rheumatic drugs, including MTX. Cimzia® can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate.[3]

In addition the European Commission has recently approved Cimzia® for the treatment of adult patients with severe active axial spondyloarthritis (axSpA) comprising:
Ankylosing spondylitis (AS) - adults with severe active AS who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs)
Axial spondyloarthritis without radiographic evidence of AS - adults with severe active axSpA without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to NSAIDs.

Notes to editors

About the RAPID™-PsA study[2]

The RAPID™-PsA study is an ongoing Phase 3, multicenter, randomized, double-blind, placebo-controlled study designed to evaluate the efficacy and safety of certolizumab pegol in patients with adult onset active and progressive PsA. Patients (n=409) were randomized 1:1:1 to placebo, or 400 mg certolizumab pegol at week 0, 2 and 4 loading dose followed by either 200 mg certolizumab pegol every two weeks or 400 mg certolizumab pegol every four weeks. Patients could have had exposure to one previous tumour necrosis factor (TNF) inhibitor therapy.

About CIMZIA®

Cimzia® is the only Fc-free, 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. 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. Cimzia® is also approved in the EU for the treatment for adult patients with severe active axSpA comprising:
Ankylosing spondylitis (AS) - adults with severe active AS who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs)
Axial spondyloarthritis without radiographic evidence of AS - adults with severe active axSpA without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to NSAIDs.

UCB is also developing Cimzia® in other autoimmune disease indications. Cimzia® is a registered trademark of UCB PHARMA S.A.

Cimzia® (certolizumab pegol) EU/EEA Important Safety Information

Cimzia® was studied in 4,049 patients with RA in controlled and open label trials for up to 92 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), asthaenia, leukopaenia (including lymphopaenia, neutropaenia), eosinophilic disorder, pain (any sites), pyrexia, sensory abnormalities, hypertension, pruritus (any sites), hepatitis (including hepatic enzyme increase), injection site reactions, and nausea. Serious adverse reactions include sepsis, opportunistic infections, tuberculosis, herpes

zoster, lymphoma, leukaemia, solid organ tumours, angioneurotic oedema, cardiomyopathies (includes heart failure), ischemic coronary artery disorders, pancytopaenia, hypercoagulation (including thrombophlebitis, pulmonary embolism), cerebrovascular accident, vasculitis, hepatitis/hepatopathy (includes cirrhosis), and renal impairment/nephropathy (includes nephritis). In RA controlled clinical trials, 4.4% of patients discontinued taking Cimzia® due to adverse events vs. 2.7% 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 cytopaenia, 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. 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.

Cimzia® was studied in 325 patients with active axial spondyloarthritis in a placebo-controlled clinical trial for up to 30 months. The safety profile of axial spondyloarthritis patients treated with Cimzia® was consistent with the safety profile in RA and previous experience with Cimzia®.

Please consult the full prescribing information in relation to other side effects, full safety and prescribing information. European SmPC date of revision 18th October 2013.

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001037/WC500069763.pdf

References

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2. Mease, P., Fleischmann, R. M. *et al.* Effect of certolizumab pegol on signs and symptoms in patients with psoriatic arthritis: 24-week results of a Phase 3 double-blind randomized placebo-controlled study (RAPID-PsA) Ann Rheum Dis 2013;0:1–8. doi:10.1136/annrheumdis-2013-203696. Accessed September 2013 from http://ard.bmj.com/content/early/2013/08/28/annrheumdis-2013-203696.full.pdf
3. Cimzia® EU Summary of Product Characteristics. Accessed October 2013 from http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001037/WC500069763.pdf

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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 9000 people in approximately 40 countries, the company generated revenue of EUR 3.4 billion in 2012. 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.