RAPID™-axSpA study showed certolizumab pegol reduced signs and symptoms of axial spondyloarthritis

- First randomized, controlled, Phase 3 study of an anti-TNF to enroll patients with active axial spondyloarthritis (axSpA) including patients with both ankylosing spondylitis (AS) and axSpA without radiographic evidence of AS (nr-axSpA)\(^1\)

- Certolizumab pegol reduced the signs and symptoms in the overall study population, with improvements in the AS and nr-axSpA sub-populations\(^1\)

- In the axSpA study population certolizumab pegol improved patient-reported outcomes such as back pain, fatigue and physical functioning and also reduced arthritis-related interference with productivity in the workplace and in the household\(^2,3\)

- Certolizumab pegol is not approved for the treatment of axSpA. UCB intends to file global regulatory submissions for certolizumab pegol in axSpA by the end of 2012

Slough, UK 13th November 2012 – UCB announced extensive results from the Phase 3 study, RAPID™-axSpA, at the American College of Rheumatology’s (ACR) 2012 Annual Scientific Meeting in Washington D.C., US.

RAPID™-axSpA enrolled patients with active axial spondyloarthritis (axSpA), including patients with ankylosing spondylitis (AS) and axSpA without radiographic evidence of AS (non-radiographic axSpA [nr-axSpA]). The study showed that compared to placebo, both dosing regimens of certolizumab pegol reduced the signs and symptoms of axSpA in the overall study population with improvements observed in both the AS and nr-axSpA sub-populations.\(^1\)

"The RAPID™-axSpA study is the first randomized, controlled, phase 3 trial of an anti-TNF to include the broad axSpA population including patients with both AS and nr-axSpA,” said Professor Robert Landewé, University of Amsterdam and Atrium Medical Center Heerlen, the Netherlands. "The study showed that the disease burden was similar at baseline for the AS and nr-axSpA sub-populations. Certolizumab pegol reduced the clinical burden of axSpA, with similar reductions compared to placebo observed across both certolizumab pegol dosing regimens in both AS and nr-axSpA sub-populations."

Results also indicated that certolizumab pegol decreased arthritis interfering with productivity in the workplace and in the household, reduced inflammation in the sacroiliac joint and spine, and improved patient-reported outcomes such as back pain, fatigue and physical functioning.\(^2,3,4\)

"AxSpA is a debilitating condition that primarily presents in a young, active population and comprises of a spectrum of clinical symptoms, with the main one being chronic inflammatory back pain,” said Professor Deodhar, Medical Director, Rheumatology Clinics Division of Arthritis & Rheumatic Diseases, Oregon Health & Science University, U.S. "People living with AS have X-ray evidence of structural damage in the sacroiliac joints and are the most well-defined sub-population, while patients with axSpA without radiographic evidence of AS are less well acknowledged today.”
Certolizumab pegol is not approved for the treatment of axSpA. UCB intends to file global regulatory submissions for certolizumab pegol in axSpA by the end of 2012.

Adverse events occurred in 70.4% vs. 62.6% of certolizumab pegol (combined dose) treated patients vs. placebo, serious AEs in 4.7% vs. 4.7% and serious infections in 1.1% vs. 0.1. The most common adverse events (occurred in >5% of patients taking certolizumab pegol or placebo) were nasopharyngitis, upper respiratory tract infection, increased creatine phosphokinase and headache.

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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, leukopaenia (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.

About RAPID™-axSpA

The ongoing 158 week RAPID™-axSpA study is double-blind and placebo-controlled up to week 24, dose-blind up to week 48 and then open-label to week 158. Patients (n=325) with active axSpA were randomized 1:1:1 to receive certolizumab pegol 200 mg every two weeks, 400 mg every four weeks or placebo (n=111, 107 and 107). This dosing schedule followed a loading dose of certolizumab pegol (400 mg) at weeks 0, 2 and 4. Patients enrolled in the study must have failed at least one non-steroidal anti-inflammatory drug (NSAID). Up to 40% of patients could have received one previous anti-TNF, provided they were not primary non-responders, as determined by the investigator. Within the placebo arm, patients who failed to achieve an ASAS20 response at weeks 14 and 16 were re-randomized at week 16 to receive certolizumab pegol 200 mg every 2 weeks or 400 mg every 4 weeks, following the loading dose.

About SpA and axSpA

SpA is the overall name of a family of inflammatory rheumatic diseases that can affect the spine and joints, ligaments and tendons. There are two main types of clinical presentation of SpA – axSpA (symptoms predominantly related to the spine) and peripheral SpA (symptoms predominantly related to the peripheral joints).

About AS

AS is a chronic inflammatory rheumatic disease of the spine and is the most defined subset of axSpA. The symptoms of AS can vary, but most people experience back pain and stiffness due to inflammation which can proceed to fusion of the vertebrae. The condition can be severe, with around 1 in 10 people at risk of long-term disability. The condition usually occurs between 15 and 35 years of age, and rarely starts in old age, with prevalence estimated to be between 0.1% - 1.1% of the population. AS is more common in men than in women.

About axSpA without radiographic evidence of AS

Patients with no definitive sacroiliitis on conventional radiographs but similar clinical features and showing either sacroiliitis on MRI or who are HLA-B27 positive have axSpA without radiographic evidence of AS (non-radiographic axSpA [nr-axSpA]).

About ASAS20

The Assessment of SpondyloArthritis international Society (ASAS20) improvement criteria is defined as an improvement of at least 20% and absolute improvement of at least one unit on a 0-10 scale in...
at least three of the four following domains: patient global assessment, pain assessment, patient function, and inflammation and the absence of deterioration in the remaining domain.

References


5. UCB Data on file

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.