UCB News

CIMZIA® (certolizumab pegol) now Available for Patients in Japan living with Multiple Psoriatic Diseases

- Approval in Japan is based on a late stage clinical trial, which confirmed the efficacy, safety, and durability of response with CIMZIA in Japanese patients with plaque psoriasis, psoriatic arthritis, pustular psoriasis and psoriatic erythroderma
- This milestone marks the continued expansion of CIMZIA in important markets and reinforces UCB's commitment in dermatology

Brussels, Belgium – 28 January, 07:00 CET – UCB announced today that it received approval from Japanese health authorities for CIMZIA® (certolizumab pegol) to treat plaque psoriasis, psoriatic arthritis, pustular psoriasis and psoriatic erythroderma for which existing treatment methods are not sufficiently effective. The approval makes CIMZIA the first Fc-free, PEGylated anti-TNF treatment option now available for these patients in Japan.

"UCB is thrilled to see the continued expansion of CIMZIA for patient populations with unmet needs in an important market like Japan. This approval and launch provide Japanese psoriasis and psoriatic arthritis patients and their physicians with a highly effective new biologic option that provides durable disease control. This milestone reinforces our commitment to improving care for people living with these challenging psoriatic diseases," said Emmanuel Caeymaex, Head of Immunology & US Solutions and Executive Vice President, UCB.

The approved dose for CIMZIA in adult patients is 400 mg every 2 weeks. For maintenance dosing, 200 mg every 2 weeks or 400 mg every 4 weeks can be considered. CIMZIA can be administered subcutaneously using the pre-filled syringe or the AutoClicks® Prefilled Pen.

This approval is based on the results of a Phase 2/3 double-blind, comparative study of Japanese patients with moderate-to-severe plaque psoriasis (including psoriatic arthritis), pustular psoriasis and psoriatic erythroderma.

Patients in the study were randomized to receive a 400 mg dose of CIMZIA every two weeks, a 200 mg dose of Cimzia every two weeks (with a starting dose of 400 mg at Week 0, 2 and 4), or placebo. In the 200 mg and 400 mg groups at week 16, 70.8% and 86.8% of patients achieved PASI 75, respectively, and 52.1% and 75.5% of patients achieved PASI 90, respectively. These results were statistically significantly higher than the placebo group (7.7% for PASI 75 and 0.0% for PASI 90) at week 16.[1]

In the 200 mg every two weeks, 400 mg every two weeks, and 400 mg every four weeks groups at week 52, 69.2%, 86.3%, and 85.0% of patients achieved PASI 75, respectively, and 57.7%, 84.3%, and 70.0% achieved PASI 90, respectively, demonstrating the durability of response with CIMZIA. The safety profile was similar to safety results observed in non-

Japanese psoriasis patients and the approved indication for patients with rheumatoid arthritis.[1]

CIMZIA was launched in Japan in March 2013 for rheumatoid arthritis. The product is manufactured and supplied by UCB for exclusive distribution and marketing by Astellas Pharma Inc., and is jointly promoted by UCB Japan and Astellas Pharma Inc. There are approximately 430,000 psoriasis patients in Japan.[2]

For the newly approved indication of CIMZIA for psoriasis, UCB Japan will be conducting all promotional activities, thus expanding its dermatology footprint to Japan.

About Psoriasis
Psoriasis is a common, chronic inflammatory disease with primary involvement of the skin. This skin condition affects men and women of all ages and ethnicities. Psoriasis signs and symptoms can vary but may include red patches of skin covered with silvery scales; dry, cracked skin that may bleed; and thickened, pitted or ridged nails.[3]

Psoriasis is a serious global problem with at least 100 million individuals affected worldwide.[4] Unmet needs remain in the treatment of psoriasis. A population-based survey identified that approximately 30 percent of psoriasis patients reported that their primary goals of therapy, including keeping symptoms under control, reducing itching and decreasing flaking, were not met with their current treatment.[5] Failure to achieve or retain complete and lasting skin clearance negatively impacts disease progression and quality of life.[6,7]

About CIMZIA® in the EU/EEA
In the EU, CIMZIA® in combination with methotrexate (MTX) is indicated for the treatment of moderate to severe active RA in adult patients inadequately responsive to disease-modifying anti-rheumatic 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 in combination with MTX is also indicated for the treatment of severe, active and progressive RA in adults not previously treated with MTX or other DMARDs.

CIMZIA has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with MTX.

CIMZIA, in combination with MTX, is also indicated for the treatment of active psoriatic arthritis in adults when the response to previous DMARD therapy has been inadequate. CIMZIA can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate.

Cimzia is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

CIMZIA is also indicated in the EU for the treatment of adult patients with severe active axial spondyloarthritis (axSpA), comprising:

- Ankylosing spondylitis (AS) (also known as non-radiographic axial spondyloarthritis) – 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 (also known as non-radiographic axial spondyloarthritis) – adults with severe active axSpA without radiographic evidence of AS but with objective signs of inflammation by elevated C-reactive protein (CRP) and/or Magnetic Resonance Imaging (MRI) who have had an inadequate response to, or are intolerant to NSAIDs.

CIMZIA® (certolizumab pegol) EU/EEA* Important Safety Information

Cimzia® was studied in 4,049 patients with rheumatoid arthritis (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 zoster, papillomavirus, influenza), bacterial infections (including abscess), rash, headache (including migraine), asthenia, leukopenia (including lymphopenia, neutropenia), 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 (including miliary, disseminated and extrapulmonary), herpes zoster, lymphoma, leukaemia, solid organ tumours, angioneurotic oedema, 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, 4.4% of patients discontinued taking Cimzia® due to adverse events vs. 2.7% for placebo.

Cimzia® was studied in 325 patients with active axial spondyloarthritis (axSpA) in a clinical study for up to 4 years which included a 24-week placebo-controlled phase followed by a 24-week dose-blind period and a 156-week open-label treatment period and in 317 patients with non-radiographic axial spondyloarthritis in a placebo-controlled study for 52 weeks (AS0006).

Cimzia® was studied in 409 patients with psoriatic arthritis (PsA) in a clinical study for up to 4 years which included a 24-week placebo-controlled phase followed by a 24-week dose-blind period and a 168-week open-label treatment period.

The safety profile for axSpA and PsA patients treated with Cimzia® was consistent with the safety profile in RA and previous experience with Cimzia®.

Cimzia® was studied in 1112 patients with psoriasis in controlled and open-label studies for up to 18 months. The safety profile of Cimzia® 400 mg every 2 weeks and Cimzia® 200 mg every 2 weeks were generally similar.

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, and moderate to severe heartfailure.

Serious infections including sepsis, tuberculosis and opportunistic infections (e.g. histoplasmosis, nocardia, candidiasis) have been reported in patients receiving Cimzia®. Some of these events have been fatal. 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®.

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 including multiple sclerosis; of formation of autoantibodies and uncommonly of the development of a lupus-likle 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 haematologic system, including medically significant cytopenia, have been 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® shouldnot 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.

Please consult the full prescribing information in relation to other side effects, full safety and prescribing information.

European SmPC date of revision June 2019.
https://www.ema.europa.eu/en/documents/product-information/cimzia-epar-product-information_en.pdf

CIMZIA® is a registered trademark of the UCB Group of Companies.

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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 in immunology or neurology. With more than 7 500 people in approximately 40 countries, the company generated revenue of € 4.5 billion in 2017. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

Forward looking statements - UCB
This press release contains forward-looking statements including, without limitation, statements containing the words “believes”, “anticipates”, “expects”, “intends”, “plans”, “seeks”, “estimates”, “may”, “will”, “continue” and similar expressions. These forward-looking statements are based on current plans, estimates and beliefs of management. All statements, other than statements of historical facts, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, arbitration, political, regulatory or clinical results or practices and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and assumptions which might cause the actual results, financial condition, performance or achievements of UCB, or industry results, to differ materially from those that may be expressed or 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 or within expected timing, 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, safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, product liability claims, challenges to patent protection for products or product candidates, competition from other products including biosimilars, 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. There is no guarantee that new product candidates will be discovered or identified in the pipeline, or that new indications for existing products will be developed and approved. Movement from concept to commercial product is uncertain; preclinical results do not guarantee safety and efficacy of product candidates in humans. So far, the complexity of the human body cannot be reproduced in computer models, cell culture systems or animal models. The length of the timing to complete clinical trials and to get regulatory approval for product marketing has varied in the past and UCB expects similar unpredictability going forward. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to disputes between the partners or may prove to be not as safe, effective or commercially successful as UCB may have believed at the start of such partnership. UCB' efforts to acquire other products or companies and to integrate the operations of such acquired companies may not be as successful as UCB may have believed at the moment of acquisition. Also, UCB or others could discover safety, side effects or manufacturing problems with its products and/or devices after they are marketed. The discovery of significant problems with a product similar to one of UCB's products that implicate an entire class of products may have a material adverse effect on sales of the entire class of affected products. Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment, including pricing pressure, political and public scrutiny, customer and prescriber patterns or practices, and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement activities and outcomes. Finally, a breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of UCB's data and systems.

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REFERENCES

[1] Approved Product Information Sheet. Japan. 2019.
[2] Kubota K. et al. BMJ Open. 2015 Jan 14;5(1)
[3] International Federation of Psoriasis Associations. Available at: https://ifpa-pso.com/our-cause//. Last accessed: December 2019.
[4] World Health Organization. (2016). Global report on psoriasis. World Health Organization. https://apps.who.int/iris/handle/10665/204417
[5] Lebwohl MG, Kavanaugh A, Armstrong AW et al. US Perspectives in the Management of Psoriasis and Psoriatic Arthritis: Patient and Physician Results from the Population-Based Multinational Assessment of Psoriasis and Psoriatic Arthritis (MAPP) Survey. Am J Clin Dermatol. 2016; 17(1):87-97.
[6] Zachariae H, Zachariae R, Blomqvist K, et al. Quality of life and prevalence of arthritis reported by 5,795 members of the Nordic Psoriasis Associations. Data from the Nordic Quality of Life Study. Acta Derm Venereol. 2002;82:108113.
[7] Moon HS, Mizara A, McBride SR. Psoriasis and psycho-dermatology. Dermatol Ther (Heidelb). 2013;3:117-130.