

UCB Launches CIMZIA® (certolizumab pegol) in China, a New Biologic Treatment Approved for Patients with Moderate to Severe Rheumatoid Arthritis

- CIMZIA® is the only Fc-free, PEGylated anti-TNF approved in China, in combination with MTX for the treatment of moderate-to-severe active rheumatoid arthritis in adult patients when the response to disease-modifying antirheumatic drugs including MTX, has been inadequate.
- CIMZIA® is the first anti-TNF for potential use in women with Rheumatoid arthritis during both pregnancy and lactation if clinically needed. As MTX is contraindicated during pregnancy, Cimzia® can be used with other DMARDs that are compatible with pregnancy.
- The first prescription of Cimzia® was issued on November 5th, allowing UCB to better serve patients living with autoimmune diseases, especially women, with this new treatment option.
- The launch of CIMZIA® reinforces UCB's ongoing commitment to supporting patient value across China. Through a pioneering partnership with Cinkate, a well-established Chinese pharmaceutical company in rheumatology, UCB will be exploring new models to bring innovative solutions to patients promptly and precisely.

Shanghai, China, December 14, 2019—Belgium-based global bio-pharmaceutical company UCB announced today the commercial launch of its innovative medicine CIMZIA® (certolizumab pegol) in China. On November 5th, the first prescription was issued, bringing a new treatment option for people living with moderate-to-severe active rheumatoid arthritis (RA) in China, especially women. The launch of the first biologic therapy in UCB's portfolio in China reinforces UCB's ongoing commitment to supporting patient value across China.

RA is an autoimmune disease that causes chronic joint inflammation, with figures suggesting China has around 5 million citizens affected with the condition. There are three times the number of women with RA than men, with those of childbearing age not only suffering from pain, but also faced with the choice of postponing or compromising family plans due to the impact of the disease.

"Reproduction is a basic right for all women, yet RA has a huge negative impact on a woman's right before, during and after pregnancy. If RA patients are incapable of controlling the symptoms of the disease, it will decrease the chances of a pregnancy occurring. The disease may also increase the risk of adverse pregnancy outcomes, such as preterm birth, low birth weight, and preeclampsia. In addition, RA carries an increased risk of disease relapse after birth, causing the mother to suffer from even more severe pain, with possible severe functional impairments and breastfeeding difficulties. An effective and well tolerated RA treatment may help serve the unmet needs of childbearing age women and help satisfy a difficulty faced by rheumatologists," said Professor Tian Xinping, Secretary of the Chinese Rheumatology Association, and Chief Physician of the Department of Rheumatology and Immunology of the Peking Union Medical College Hospital.

CIMZIA® (certolizumab pegol) is the only Fc-free, PEGylated anti-TNF with a high affinity for human TNF-alpha, which shows a rapid onset of response and sustained effects in reducing the signs and symptoms of rheumatoid arthritis with minimal placental transfer. Due to its unique molecular structure and positive clinical trial results, CIMZIA® is the first anti-TNF for potential use in women with rheumatoid arthritis during both pregnancy and lactation if clinically needed.

"In recent years, the launch of biologics has brought new hope for RA treatment in China. However, treat-to-target effectiveness of RA patients in China is still low and the clinical remission rate after a year of treatment is only 22%. Improving the treatment outcome for women of childbearing age is especially urgent: existing

treatments require constant adjustment during a patient's journey, with the current range proving ineffective at bringing the disease under control in some women of child-bearing age. Certolizumab pegol has effectively filled the gap in clinical treatment in China. Based on the results of clinical trials, certolizumab pegol may be considered for the treatment of RA patients during pregnancy and lactation if clinically needed, by the European League Against Rheumatism (EULAR); The British Society for Rheumatology and the British Health Professionals in Rheumatology committee (BSR/BHPR), and the Asia Pacific League of Associations for Rheumatology (APLAR) provide the same recommendations. CIMZIA® will also help to increase the remission rate of the condition and provide a new solution for female patients of childbearing age," said Professor Li Zhanguo from Peking University People's Hospital, Former President of the Asia Pacific League of Associations for Rheumatology, Former Chair of the Chinese Rheumatology Association.

"Around 150,000 patients with autoimmune diseases globally have benefited from CIMZIA® and we are delighted to bring this novel medicine to Chinese patients living with challenging chronic inflammatory conditions. UCB has a long heritage in immunology and now China has built an active pipeline of innovative portfolios reflecting UCB's global strengths. As part of our transition to an agile biopharma model, we are pleased to partner with Cinkate to support patients suffering from severe immunological conditions with leading digital solutions based on patient insights and maximized Physician-Patient interaction for better disease management," said Taco van Tiel, Vice President and Head of International Markets, UCB.

CIMZIA® is now available in many hospitals and pharmacies across China. For further information, patients may follow the WeChat Official Account "HOPEC", launched by the China Health Promotion Foundation.

Taking advantage of China's favorable policies for innovative drugs, two of UCB's late stage pipeline assets - one for the treatment of highly drug-resistant epilepsy and one for the treatment of autoimmune diseases – have received CTA approvals in the first half of 2019 to begin phase III clinical trials in China together with other sites across the globe. On December 4th, 2019, UCB received another clinical trial notification letter from Center for Drug Evaluation (CDE) for a biological drug for the treatment of osteoporosis. Meanwhile, UCB has been actively seeking local cooperation opportunities to explore various possibilities of "internet+" healthcare. On November 21st, UCB and JD Health signed a strategic cooperation memorandum to improve experiences throughout the patient journey, to build a bridge for innovation "from global to China and from China to global."

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 also indicated in the EU 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 (axSpA) without radiographic evidence of AS – 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 is also indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

About CIMZIA® in Fertility, Pregnancy and Lactation in the EU/EEA

Women of childbearing potential

The use of adequate contraception should be considered for women of childbearing potential. For women planning pregnancy, continued contraception may be considered for 5 months after the last CIMZIA dose due to its elimination rate, but the need for treatment of the woman should also be taken into account (see below).

Pregnancy

Data from more than 500 prospectively collected pregnancies exposed to CIMZIA with known pregnancy outcomes, including more than 400 pregnancies exposed during the first trimester, does not indicate a malformative effect of CIMZIA. However, the available clinical experience is too limited to, with a reasonable certainty, conclude that there is no increased risk associated with CIMZIA administration during pregnancy.

Animal studies using a rodent anti-rat TNF α did not reveal evidence of impaired fertility or harm to the foetus. However, these are insufficient with respect to human reproductive toxicity. Due to its inhibition of TNF α , CIMZIA administered during pregnancy could affect normal immune response in the newborn.

CIMZIA should only be used during pregnancy if clinically needed. Non-clinical studies suggest low or negligible level of placental transfer of a homologue Fab-fragment of certolizumab pegol (no Fc region).

In a clinical study 16 women were treated with certolizumab pegol (200 mg every 2 weeks or 400 mg every 4 weeks) during pregnancy. Certolizumab pegol plasma concentrations measured in 14 infants at birth were Below the Limit of Quantification (BLQ) in 13 samples; one was 0.042 μ g/ml with an infant/mother plasma ratio at birth of 0.09%. At Week 4 and Week 8, all infant concentrations were BLQ. The clinical significance of low levels certolizumab pegol for infants is unknown. It is recommended to wait a minimum of 5 months following the mother's last CIMZIA administration during pregnancy before administration of live or live-attenuated vaccines (e.g. BCG vaccine), unless the benefit of the vaccination clearly outweighs the theoretical risk of administration of live or live-attenuated vaccines to the infants.

Breastfeeding

In a clinical study in 17 lactating women treated with CIMZIA, minimal transfer of certolizumab pegol from plasma to breast milk was observed. The percentage of the maternal certolizumab pegol dose reaching an infant during a 24 hour period was estimated to 0.04% to 0.30%. In addition, since certolizumab pegol is a protein that is degraded in the gastrointestinal tract after oral administration, the absolute bioavailability is expected to be very low in a breastfed infant. Consequently, CIMZIA can be used during breastfeeding.

Important Safety Information about CIMZIA® in the EU/EEA

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 herpeszoster, 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 (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® 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 heart failure.

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. 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® until the infection is controlled. 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, including multiple sclerosis; 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 haematologic system, including medically significant cytopaenia, 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® 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 (axSpA) and in 409 patients with psoriatic arthritis (PsA) for up to 4 years. 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.

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/documents/product-information/cimzia-epar-product-information_en.pdf

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

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 7 500 people in approximately 40 countries, the company generated revenue of € 4.6 billion in 2018. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news.

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 a guarantee 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.

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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.

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