UCB receives positive EU CHMP opinion for CIMZIA® (certolizumab pegol) AutoClicks® Prefilled Pen

Brussels, Belgium – September, 2016 – UCB has announced that the European Medicines Agency's (EMA's) Committee for Medicinal Products for Human Use (CHMP) has recommended the use of CIMZIA® AutoClicks® Prefilled Pen in all approved indications. The positive opinion was based on validated data and risk benefit analysis for the AutoClicks® Prefilled Pen.

"At UCB, we have made it a priority to develop a true understanding of the real world challenges for people living with severe rheumatologic conditions and to determine the best solutions. The availability of the AutoClicks® Prefilled Pen will allow us to provide different administration options for patients treated with CIMZIA®. Patients have personal preferences for self-injection devices depending on their experience and individual needs, so having a prefilled pen and syringe will better support patients," said Emmanuel Caeymaex, Head of Immunology and Executive Vice President at UCB, Immunology Patient Value Unit, UCB.

UCB is committed to providing value to patients and meeting their unique needs. As part of this commitment, UCB continued its partnership with OXO, a company known for thoughtful, consumer friendly designs, to develop the AutoClicks® Prefilled Pen, based on core technology licensed from Bespak. The AutoClicks® Prefilled Pen provides a button-free delivery system and a wide non-slip grip that keeps patient hand disability in mind. It has a large viewing window that shows the progress of the injection and it makes a clicking noise at the start of the injection and again when the injection is complete, giving patients confidence to know they have received their full dose of CIMZIA®.

Research was conducted to ensure that the AutoClicks® Prefilled Pen would meet the needs of patients living with autoimmune diseases like rheumatoid arthritis. In a comparative usability study with 76 moderate to severe rheumatoid arthritis (RA) patients simulating an injection using an injection pad, the RA patients gave the highest rankings to the AutoClicks® Prefilled Pen as the most preferred prefilled pen. Patients in the study also evaluated the AutoClicks® Prefilled Pen on a seven point scale for its ease of use and their willingness to use it in the future, giving it the highest score on the scale compared to Enbrel® (etanercept), Humira® (adalimumab) and Simponi® (golimumab) anti-TNF prefilled pens ($p<0.05$).[2] The patients in the study had no prior experience using an anti-TNF prefilled pen. All identification was removed from the prefilled pen devices and the instructions for use. Devices tested at time of study were approved for use in the UK.[1]

About OXO

Founded in 1990 on the concept of Universal Design, OXO's mission is to create consumer household products that ease the tasks of everyday life for the widest range of users possible. Since the original 15 Good Grips items were introduced, the OXO collection has grown to more than 1,000 strong, covering many rooms of the house and tasks including cooking, baking, cleaning, brewing coffee, storing, organizing, childcare and more. Headquartered in New York City, the company's products are sold in more than 80 countries and are included in the permanent collections of numerous museums. The company has won more than 100 design and business awards worldwide and is frequently used as a case study on how a well-executed Universal Design philosophy can be a successful business strategy.

OXO and Good Grips® are trademarks owned and/or licensed by Helen of Troy Limited (NASDAQ, NM: HELE), and are used by UCB under license.

About Bespak
Bespak, a Consort Medical company, is a full-service drug delivery partner, specialising in innovative patient-centric medical devices. With nearly 60 years' experience in drug delivery Bespak applies its proven know how and technologies to address the ever changing needs of the pharmaceutical industry, across multiple applications.

Bespak partners with customers to design and develop drug delivery devices, as well as providing contract device manufacturing from pilot to commercial scale. As part of the Consort Medical Group, Bespak works with its Aesica colleagues to offer customers an accelerated route to market through a streamlined service, at any stage of the development cycle.

For more information, please visit: http://www.bespak.com

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.

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 methotrexate or when continued treatment with methotrexate 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.[4]

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 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 (axSpA) in a placebo-controlled clinical trial for up to 30 months and in 409 patients with psoriatic arthritis (PsA) in a placebo-controlled clinical trial for up to 30 months. The safety profile for axSpA and PsA 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 17th December 2015. http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001037/WC500069763.pdf

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

REFERENCES

1. **UCB. Data on file (Comparative Usability and Validation Study for CIMZIA® pre-filled pen - Study Report, Sections 8.2.1.1, 8.2.2.4, and 8.2.2.5). 2013.**
2. **Domanska B et al. Ann Rheum Dis. 2016;75(Suppl2):1002. Abstract AB0300**

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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 7

700 people in approximately 40 countries, the company generated revenue of € 3.9 billion in 2015. 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 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.