UCB News

UCB Gains CE Mark for ava Connect®, a first-in-class electromechanical device for use with biologic treatment in rheumatology and dermatology

ava Connect® is designed to help improve the patient experience and medication adherence for CIMZIA® (certolizumab pegol) by providing a comfortable injection and recording the patient's injection administration, visualized on the CimplyMe® companion app

Brussels, Belgium – March 19, 2021 – UCB, a global biopharmaceutical company, today announced that its first-in-class electromechanical injection device, ava Connect®, has received its Declaration of Conformity (CE) Mark.[1] The CE Mark indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA).[2]

The ava Connect® and disposable dose-dispenser cartridge are used for self-injecting CIMZIA® (certolizumab pegol), an anti-TNF therapy used to treat adults with rheumatoid arthritis, axial spondyloarthritis, psoriatic arthritis, and psoriasis (see About CIMZIA section below for complete indication information). It is the first reusable device of its kind available for use with biologic treatment in rheumatology and dermatology in Europe.[3] To accompany ava Connect® and further support patients, UCB has also developed CimplyMe®, a companion mobile application. Both are part of UCB's mission to transform the way patient support is delivered and accelerate better outcomes for people living with severe diseases as part of its digital business transformation.

"At UCB, we are increasing our ability to provide differentiating patient value with advanced technology solutions. With the recent acceleration of telemedicine, ava Connect® and CimplyMe® can help improve the patient experience and help to make it easier to connect with healthcare providers outside of face-to-face consultations by providing symptom and treatment adherence monitoring reports. With these technological innovations, UCB aims to be a pioneer in digital medicine for rheumatology and dermatology patients," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of US, UCB.

The ava Connect® e-device has been developed together with patients to address injection and treatment management challenges that can lead to low persistency.[4,5] Up to 68 percent of self-injecting patients are non-compliant at one year of treatment, resulting in increased healthcare resource utilization (e.g. hospitalizations, inpatient visits, treatment cost, etc.) due to suboptimal treatment outcomes.[6] This observation is based on 19 studies reporting compliance data covering rheumatoid arthritis and Crohn's disease patients treated with infliximab, adalimumab, golimumab and etanercept.

The device has a hidden needle and non-slip hand grip to assist patients with dexterity issues. The large start/pause button and injection speed choice give patients control over their injections. The information screen allows patients to access step-by-step instructions, confirms injection completion and provides injection date notifications.[7] Studies have demonstrated that patients find the e-device easy to use and are satisfied with their self-injection experience.[8]

The ava Connect® e-device also logs injection dates, allowing it to record objectively patient adherence, which can be shared with clinicians. Skin sensors automatically stop an injection if skin contact is lost and the needle is retracted within the device. After re-positioning, the injection can continue, preventing medication waste and helping to ensure the patient receives the full dose. Safety features ensure that the medication cartridge is automatically checked for drug identity, expiry status, and use status before an injection is given.[7]

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CimplyMe®, the companion mobile application for ava Connect®, enables a treatment experience for patients that takes a holistic approach to chronic disease management. By using CimplyMe® with ava Connect®, patients will be able to access their injection data, disease management and treatment information, and track and monitor their disease symptoms, as well as receive injection reminders. The ava Connect® device can be paired with CimplyMe® via a smartphone Bluetooth.

CimplyMe® can create reports that patients can share with their healthcare providers, aiming to support patients to have more efficient consultations and informed treatment decisions with their healthcare providers guided by the health metrics and objective injection log.

The ava Connect® e-device is part of a portfolio of CIMZIA self-injection devices that includes the CIMZIA® pre-filled syringe and the AutoClicks® pre-filled pen. The portfolio aims to provide to HCPs and patients the choice to identify together the right device for the unmet patient needs and hence to help improve patient self-injection experience, help increase adherence and potentially improve clinical outcomes. UCB continued its partnership with OXO, a company known for thoughtful, consumer friendly designs, to develop the ava Connect® e-device.

About OXO
Founded in 1990 on the concept of inclusive universal design, OXO creates household products that make everyday task and chores better. The OXO portfolio spans several categories: cooking, baking, cleaning, storage and organization, coffee and baby. OXO is available in 90 countries worldwide; its iconic products are included in the permanent collections of numerous museums, including the Museum of Modern Art and the Smithsonian Cooper Hewitt National Design Museum. The brand has won over 100 design awards worldwide.

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 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

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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.

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

Date of revision March 2021

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 initially studied in 325 patients with active axial spondyloarthritis (including ankylosing spondylitis and non-radiographic axial spondyloarthritis) in the AS001 clinical study for up to 4 years, which includes a 24-week placebo-controlled phase followed by a 24-week dose-blind period and a 156-week open-label treatment period. Cimzia was subsequently studied in 317 patients with non-radiographic axial spondyloarthritis in a placebo-controlled study for 52 weeks (AS0006). Cimzia was also studied in patients with axial spondyloarthritis (including ankylosing spondylitis and non-radiographic axial spondyloarthritis) in a clinical study for up to 96 weeks, which included a 48-week open-label run-in phase (N=736) followed by a 48-week placebo-controlled phase (N=313) for patients in sustained remission (C-OPTIMISE). In all 3 studies, the safety profile for these patients was consistent with the safety profile in rheumatoid arthritis and previous experience with Cimzia.

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 3 years. In the Phase III program, the initial and maintenance periods were followed by a 96-week open-label treatment period. The long-term safety profile of Cimzia® 400 mg every 2 weeks and Cimzia® 200 mg every 2 weeks was generally similar and consistent with previous experience with Cimzia.

*EU/EEA means European Union/European Economic Area

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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. 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-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 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® 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.

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

European SmPC date of revision March 2021.
https://www.ema.europa.eu/en/documents/product-information/cimzia-epar-product-information_en.pdf
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