



## Partnership unites UCB with consumer product innovator OXO®

- UCB offers Cimzia® (*certolizumab pegol*), a treatment option for adults with moderately to severely active rheumatoid arthritis and moderate to severe Crohn's disease, to U.S. patients in an exclusively designed prefilled syringe resulting from the UCB partnership with OXO®
- Rheumatoid arthritis patients directly involved with UCB and OXO® in the development of the new Cimzia® prefilled syringe
- Cimzia® prefilled syringe designed to make self-administration easy for people living with rheumatoid arthritis

**BRUSSELS (14 May, 2009 – 07.00 AM CEST)** – In a long-term partnership agreement, UCB, a global biopharmaceutical leader, has teamed up with OXO®, a celebrated consumer products company, to offer patients a syringe and packaging components that take into account some of the challenges many rheumatoid arthritis (RA) patients face when self-administering their medicine. UCB's Cimzia® (*certolizumab pegol*) was approved this week by the U.S. Food and Drug Administration (FDA) and offers a treatment option for adults with moderately to severely active rheumatoid arthritis. Cimzia® is also approved for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderate to severely active disease who have had an inadequate response to conventional therapy. The new prefilled syringe is now also available to U.S. Crohn's patients taking Cimzia® for subcutaneous self-administration. The new syringe carries the Arthritis Foundation's Ease-of-Use Commendation, signifying a positive review of the syringe design by the Arthritis Foundation's™ independent research laboratory.

The companies recognized the importance of designing a syringe and packaging components that take into account many of the dexterity challenges RA patients may face. The prefilled syringe resulting from the partnership with OXO® was designed for use by patients with different grip styles and strengths.

"This syringe, a result of our partnership with OXO®, demonstrates UCB's commitment to patients with severe diseases. I am proud of the fact that people living with rheumatoid arthritis worked directly with the design and engineering teams to develop this syringe. We have designed a syringe that takes into account some of the challenges that come with self-injection. UCB has gone beyond providing a new effective treatment option. Our long-term partnership with OXO® will allow us to help make everyday living easier for rheumatoid arthritis patients." said Roch Doliveux, Chief Executive Officer of UCB. "In addition, we are pleased to offer people with Crohn's disease in the U.S. the option of self-administering Cimzia® using this newly designed syringe. Cimzia® patients will now have the convenience of at-home self-injections," said Doliveux.



“OXO<sup>®</sup> was built on the foundation of Universal Design, which focuses on creating easy and comfortable-to-use products for the widest spectrum of users possible,” said Alex Lee, President of OXO<sup>®</sup>. “In partnering with UCB, we were able to apply our design principles in a new setting. The result is a prefilled syringe that helps provide comfort and control for a wide variety of patient self-administration abilities and user styles.”

### **The Design Process**

The development of UCB’s new prefilled syringe was initiated when UCB patient research identified that self-injection was a challenge for many people with RA.

UCB and OXO<sup>®</sup> brought in patients to assess the syringes available in the market place and the UCB prototype. This led to the redesign of many aspects of the syringe and its packaging. Specifically, the prefilled syringe, which is available for use with Cimzia<sup>®</sup>, is designed with the following in mind:

- **Easy to grip wide flange (finger grips)** – soft, non-slip grip allows patients to hold the syringe steady using various grip positions.
- **Easy to remove needle cover** – rounded finger loop for easy removal of needle cover; flared needle cap designed to reduce needle pricks due to recoil.
- **Easy to push syringe plunger** – large and soft thumb pad for patients to push the plunger.
- **Easy to read syringe barrel** - magnified barrel helps ensure patients receive entire dose as they can see the medicine inside and know when they have injected all of it.
- **Easy to grip elliptical barrel** – elliptical barrel for patients to grip and helps prevent slippage during patient handling.
- **Easy to open packaging** - the cover with a rounded corner uses Velcro<sup>®</sup> for easy opening and resealing; large, easy-to-read directions and clear visuals instruct patients how to use the pack and administer/inject Cimzia<sup>®</sup>; and lastly, the plastic housing inside with a large finger recess allows patients to easily remove the syringe.

### **Cimzia<sup>®</sup> safety information**

Reported serious adverse reactions of Cimzia<sup>®</sup> were infections (including tuberculosis and histoplasmosis) and malignancies including lymphoma. The most commonly occurring adverse events were upper respiratory tract infections, rash and urinary tract infections. A pooled analysis of the safety data show there was a low incidence of injection site pain (<2%) and a low level of discontinuations due to adverse events (5%).

#### ***For further information***

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## **Notes to the editor**

### **About Cimzia®**

*Cimzia® is the only PEGylated anti-TNF (Tumour Necrosis Factor). Cimzia® has a high affinity 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 pathological inflammation, and excess TNF-alpha production has been directly implicated in a wide variety of diseases. The U.S. Food and Drug Administration (FDA) has approved Cimzia® for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderate to severe active disease who have had an inadequate response to conventional therapy and for the treatment of adults with moderate to severely active rheumatoid arthritis. Cimzia® was approved in Switzerland for induction of a clinical response and for the maintenance of a clinical response and remission in patients with active Crohn's disease who have not responded adequately to conventional treatment in September 2007. UCB is also developing Cimzia® in other autoimmune disease indications. Cimzia® is a registered trademark of UCB PHARMA S.A.*

### **IMPORTANT SAFETY INFORMATION**

*Patients treated with CIMZIA are at an increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. CIMZIA should be discontinued if a patient develops a serious infection or sepsis.*

*Reported infections include:*

- *Active tuberculosis, including reactivation of latent tuberculosis. Patients with tuberculosis have frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent tuberculosis before CIMZIA use and during therapy. Treatment for latent infection should be initiated prior to CIMZIA use.*
- *Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Empiric anti-fungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness.*
- *Bacterial, viral and other infections due to opportunistic pathogens.*

*The risks and benefits of treatment with CIMZIA should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection. Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with CIMZIA, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.*



*Serious and sometimes fatal infection due to bacterial, mycobacterial, invasive fungal, viral or other opportunistic pathogens has been reported in patients receiving TNF-blocking agents. Among opportunistic infections, tuberculosis, histoplasmosis, aspergillosis, candidiasis, coccidioidomycosis, listeriosis, and pneumocystosis were the most common. Treatment with CIMZIA should not be initiated in patients with an active infection, including clinically important localized infections. The risks and benefits of treatment should be considered prior to initiating therapy in patients with chronic or recurrent infection, who have been exposed to tuberculosis, who have resided or traveled in areas of endemic tuberculosis or endemic mycoses, such as histoplasmosis, coccidioidomycosis, or blastomycosis, or with underlying conditions that may predispose them to infection.*

*Patients should be evaluated for tuberculosis risk factors and tested for latent infection prior to initiating CIMZIA and periodically during therapy. Patients should be closely monitored for the development of signs and symptoms of infections during and after treatment with CIMZIA, including development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy. CIMZIA should be discontinued if a patient develops a serious infection or sepsis. Patients who develop a new infection during treatment with CIMZIA should be closely monitored, undergo a prompt and complete diagnostic workup appropriate for immunocompromised patients, and appropriate antimicrobial therapy should be initiated. Appropriate empiric antifungal therapy should also be considered while a diagnostic workup is performed for patients who develop a serious systemic illness and reside or travel in regions where mycoses are endemic.*

*During controlled and open-labeled portions of CIMZIA studies of Crohn's disease and other disease, malignancies (excluding non-melanoma skin cancer) were observed at a rate (95% confidence interval) of 0.5 (0.4, 0.7) per 100 patient-years among 4,650 CIMZIA-treated patients versus a rate of 0.6 (0.2, 1.7) per 100 patient-years among 1,319 placebo-treated patients. The size of the control group and limited duration of the controlled portions of the studies preclude the ability to draw firm conclusions. In studies of CIMZIA for Crohn's disease and other investigational uses, there was one case of lymphoma among 2,657 CIMZIA-treated patients and one case of Hodgkin lymphoma among 1,319 placebo-treated patients. In CIMZIA RA clinical trials (placebo-controlled and open label) a total of three cases of lymphoma were observed among 2,367 patients. This is approximately 2-fold higher than expected in the general population. Patients with RA, particularly those with highly active disease, are at a higher risk for the development of lymphoma. The potential role of TNF blocker therapy in the development of malignancies is not known.*

*Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers. CIMZIA has not been formally studied in patients with CHF. Exercise caution when using CIMZIA in patients who have heart failure and monitor them carefully.*

*Symptoms compatible with hypersensitivity reactions, including angioedema, dyspnea, hypotension, rash, serum sickness, and urticaria, have been reported rarely following CIMZIA administration. If such reactions occur, discontinue further administration of CIMZIA and institute appropriate therapy.*

*Use of TNF blockers, including CIMZIA, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers of this virus. Some cases have been fatal. Evaluate patients at risk for HBV infection for prior evidence of HBV infection before initiating CIMZIA therapy. Exercise caution in prescribing CIMZIA for patients identified as carriers of HBV. Patients who are carriers of HBV and require treatment with CIMZIA should be closely monitored for clinical and laboratory signs of active HBV infection throughout therapy and for several months following termination of therapy. In patients who develop HBV reactivation, discontinue CIMZIA and initiate effective anti-viral therapy with appropriate supportive treatment.*

*Use of TNF blockers, including CIMZIA, has been associated with rare cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of demyelinating disease. Rare cases of neurological disorders, including seizure disorder, optic neuritis, and peripheral neuropathy have been reported in patients treated with CIMZIA; the causal relationship to CIMZIA remains unclear. Exercise caution in considering the use of CIMZIA in patients with these disorders.*

*Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medically significant cytopenia (e.g., leukopenia, pancytopenia, thrombocytopenia) has been infrequently reported with CIMZIA. The causal relationship of these events to CIMZIA remains unclear. 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 hematologic abnormalities.*



An increased risk of serious infections has been seen in clinical trials of other TNF blocking agents used in combination with anakinra or abatacept. Formal drug interaction studies have not been performed with rituximab or natalizumab; however because of the nature of the adverse events seen with these combinations with TNF blocker therapy, similar toxicities may also result from the use of CIMZIA in these combinations. Therefore, the combination of CIMZIA with anakinra, abatacept, rituximab, or natalizumab is not recommended.

Treatment with CIMZIA may result in the formation of autoantibodies and, rarely, in the development of a lupus-like syndrome. Discontinue treatment if symptoms of lupus-like syndrome develop.

Do not administer live vaccines or attenuated vaccines concurrently with CIMZIA.

Interference with certain coagulation assays has been detected in patients treated with CIMZIA. There is no evidence that CIMZIA therapy has an effect on in vivo coagulation. CIMZIA may cause erroneously elevated aPTT assay results in patients without coagulation abnormalities.

In controlled Crohn's clinical trials, the most common adverse events that occurred in  $\geq 5\%$  of CIMZIA patients (n=620) and more frequently than with placebo (n=614) were upper respiratory infection (20% CIMZIA, 13% placebo), urinary tract infection (7% CIMZIA, 6% placebo), and arthralgia (6% CIMZIA, 4% placebo). The proportion of patients who discontinued treatment due to adverse reactions in the controlled clinical studies was 8% for CIMZIA and 7% for placebo.

In controlled RA clinical trials, the most common adverse events that occurred in  $\geq 3\%$  of patients taking CIMZIA 200 mg every other week with concomitant methotrexate (n=640) and more frequently than with placebo with concomitant methotrexate (n=324) were upper respiratory tract infection (6% CIMZIA, 2% placebo), headache (5% CIMZIA, 4% placebo), hypertension (5% CIMZIA, 2% placebo), nasopharyngitis (5% CIMZIA, 1% placebo), back pain (4% CIMZIA, 1% placebo), pyrexia (3% CIMZIA, 2% placebo), pharyngitis (3% CIMZIA, 1% placebo), rash (3% CIMZIA, 1% placebo), acute bronchitis (3% CIMZIA, 1% placebo), fatigue (3% CIMZIA, 1% placebo). Hypertensive adverse reactions were observed more frequently in patients receiving CIMZIA than in controls. These adverse reactions occurred more frequently among patients with a baseline history of hypertension and among patients receiving concomitant corticosteroids and non-steroidal anti-inflammatory drugs. Patients receiving CIMZIA 400mg as monotherapy every 4 weeks in RA controlled clinical trials had similar adverse reactions to those patients receiving CIMZIA 200mg every other week. The proportion of patients who discontinued treatment due to adverse reactions in the controlled clinical studies was 5% for CIMZIA and 2.5% for placebo. Please see full prescribing information on [www.Cimzia.com](http://www.Cimzia.com).

#### **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 items were introduced, the OXO collection has grown to more than 800 strong covering areas for cooking, cleaning, gardening, storing, organizing and lighting. Today OXO Good Grips products are sold in 54 countries and are included in the permanent collections of numerous museums. The company has won more than 100 design and business awards worldwide. OXO is very frequently used as a case study on how a well-executed Universal Design philosophy can be a successful business strategy. OXO is owned by Helen of Troy Limited, a leading designer, producer and global marketer of brand-name personal care and household consumer products. OXO® and GOODGRIPS® are trademarks of Helen of Troy Limited and are used under license.

#### **About UCB**

UCB, Brussels, Belgium ([www.ucb.com](http://www.ucb.com)) is a biopharmaceutical company dedicated to the research, development and commercialization of innovative medicines with a focus on the fields of central nervous system and immunology disorders. Employing approximately 10 000 people in over 40 countries, UCB generated revenue of EUR 3.6 billion in 2008. 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. Such statements are subject to risks and uncertainties that may cause actual results to be materially different 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, effects of future judicial



*decisions, changes in regulation, exchange rate fluctuations and hiring and retention of its employees.*