New study finds rheumatoid arthritis (RA) patients preferred ergonomically designed Cimzia® (certolizumab pegol) syringe to conventional prefilled syringe

- **RA patients' assessment and performance capabilities showed preference for using the OXO® designed Cimzia® syringe, compared to a conventional prefilled syringe[1]**
- **More than 75% of patients were able to exert greater force using the OXO designed Cimzia® syringe and reported finding it more comfortable and easier to control[1]**

BRUSSELS, 21st September 2011, 07:00 CET– Results from a study assessing the use of the OXO designed Cimzia® (certolizumab pegol) syringe showed patients with rheumatoid arthritis (RA) rated it higher on nineteen preference and performance-based scores, when compared to the conventional prefilled syringe used in the pivotal registration study RAPID 2.[1, 2] Additionally, the results, recently published in *Applied Ergonomics*, showed that 77% of the patients involved in the study were able to exert greater force when using the OXO designed syringe compared with the conventional prefilled syringe.[1]

"If untreated the effects of RA can often limit a patient's hand strength and dexterity, which can lead to difficulties in self-administering medication at home," said Michael Schiff MD, University of Colorado, USA. "The results from this study reinforce the importance of understanding the limitations RA can impose on a person's daily activity and the importance of providing solutions to patients that will improve the everyday management of their disease."

The study assessed the effect of syringe design on the ability of RA patients to perform injections. Twenty-three RA patients participated in this study to compare preferences and injection forces using a conventional syringe and the OXO designed certolizumab pegol syringe. Injection force measurements were collected in two ways: (a) isometric forces, with the syringes' plungers in fixed positions and (b) forces exerted during injection of the medication. Subjects' grip and pinch strengths were also measured. Using a 7-point scale (1 was the worst and 7 the best rating) a perception questionnaire gauged subjects' impressions and preferences. Injections were performed using simulated skin pads. One syringe, referred to as the RAPID 2 syringe, was a standard pre-filled "off-the-shelf" syringe. The second syringe was the ergonomically designed syringe created by Smart Design, OXO, and UCB.

As part of the study, a patient questionnaire evaluated perceptions of the two prefilled syringes and compared patient views on ease-of-use, physical characteristics and general preferences across twenty different attributes. Of the twenty attributes, 15 were statistically significant at the 95% confidence level, and 16 were statistically significant at the 90% confidence level. Results showed that patients found the OXO designed syringe more comfortable (6.0 (±1.0*)) vs. 4.2 (±1.7*)) and easier to inject (5.5 (±1.3*)) vs. 4.0 (±1.8*)) than the traditional syringe.[1] Furthermore, patients agreed the OXO designed syringe provided more control (5.5 (±1.7*) vs. 4.4 (±2.0*)) and the larger design of the plunger made injections easier (5.7 (±1.7*) vs. 4.3 (±2.0*)).[1]

Designed in partnership with OXO, the certolizumab pegol prefilled syringe incorporates several key features for RA patients, including a non-slip finger grip, a finger loop on the needle shield and a larger than usual plunger. Development of the syringe was initiated when UCB patient research identified self-injection with a conventional syringe as a challenge for many people with RA.

UCB and OXO spent time discussing design features with RA patients to establish their needs as part of the design process. The result was a syringe designed specifically for patients with RA. In March 2011, the UCB/OXO prefilled syringe received the coveted GOOD DESIGN™ Award for the patient-friendly design and packaging.[3] The GOOD DESIGN™ Award is not the first that UCB has been recognised by the design industry for its Cimzia® syringe and packaging. Further design wins include; 2009 Red Dot: Communications Design Award,[4] 2009 Silver Spark Award,[5] 2010 iF Product Design Award,[6] 2010 Universal Design Award,[7] 2010 Medical Design Excellence Award (MDEA),[8] 2010 Red Dot: Product Design Award.[9]

** Standard Deviation*

References

1. *Sheikhzadeh, A., Yoon, J., Formosa, D., Domanska, B., Morgan, D., Schiff, M. The effect of a new syringe design on the ability of rheumatoid arthritis patients to inject a biological medication, Applied Ergonomics (2011), doi:10.1016/j.apergo.2011.05.014 (in press)*
2. *Smolen, J. S., et al. Efficacy and Safety of Certolizumab Pegol Plus Methotrexate in Active Rheumatoid Arthritis: The RAPID 2 Study Annals of the Rheumatic Diseases;6-1-2009;68;6;797-804.*
3. *http://www/chi-athenaeum.org/gdesign/2010/medical/609.html*
4. *http://www.smartdesignworldwide.com/news/article.php?id=169*
5. *http://www.sparkawards.com/Galleries/09_Entries.htm?appid=1926*
6. *http://www.smartdesignworldwide.com/news/article.php?id=1135*
7. *http://www.ud-germany.de/cms/ud/en/universal_design_online_exhibition/universal_design_award_2010/winn*
8. *http://www.canontradeshows.com/expo/awards/awards/index.php?catId=-1&year=2010&view=View*
9. *http://en.red-dot.org/2796.html?&cHash=86b071d0d8401a522ca75eed527643eb&detail=7380*

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About CIMZIA®
Cimzia® is the only PEGylated anti-TNF (Tumor Necrosis Factor). Cimzia® has a high affinity for human TNF-alpha, selectively neutralizing 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 moderately to severely active disease who have had an inadequate response to conventional therapy and for the treatment of adults with moderately to severely active rheumatoid arthritis. Cimzia® in combination with MTX, is approved in the EU for the treatment of moderate to severe active RA in adult patients inadequately responsive to disease-modifying antirheumatic drugs (DMARDs) including MTX. Cimzia® can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate. UCB is also developing Cimzia® in other autoimmune disease indications. Cimzia® is a registered trademark of UCB PHARMA S.A.

CIMZIA® (certolizumab pegol) in European Union / EEA important safety information
Cimzia® was studied in 2367 patients with RA in controlled and open label trials for up to 57 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), asthenia, leukopaenia (including lymphopaenia, neutropaenia), eosinophilic disorder, pain (any sites), pyrexia, sensory abnormalities, hypertension, pruritis (any sites), hepatitis (including hepatic enzyme increase), injection site reactions. Serious adverse reactions include sepsis, opportunistic infections, tuberculosis, herpes zoster, lymphoma, leukaemia, solid organ tumours, angioneurotic edema, 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, 5% of patients discontinued taking Cimzia® due to adverse events vs. 2.5% 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, moderate to severe heart failure.

Before initiation of Cimzia®, evaluate patients for both active or inactive (latent) tuberculosis infection. Monitor patients for the development of signs and symptoms of infection during and after treatment with Cimzia®. If an infection develops, monitor carefully, and stop Cimzia® if infection becomes serious.

TNF blockers including Cimzia® may increase the risk: of reactivation of Hepatitis B Virus (HBV) in patients who are chronic carriers of the virus; 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 cytopenia, 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 or attenuated 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 February 2011.

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001037/WC500069763.pdf

About UCB

*UCB, Brussels, Belgium (*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 more than 9000 people in over 40 countries, UCB produced revenue of EUR 3.22 billion in 2010. UCB is listed on Euronext Brussels (symbol: UCB).*

UCB 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 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.

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 Good Grips® are registered trademarks of Helen of Troy Limited.