

November 28, 2018

Press Release

UCB Japan Co., Ltd.

Astellas Pharma Inc.

**Cimzia® (certolizumab pegol) 200mg AutoClicks® for S.C.
Injection Newly Launched**

UCB Japan (headquarters: Shinjuku-ku, Tokyo; president: Kanako Kikuchi; hereafter referred to as “UCB Japan”; when referring to the global UCB group, “UCB”) and Astellas Pharma Inc. (headquarters: Chuo-ku, Tokyo; president and CEO: Kenji Yasukawa, Ph.D. hereafter referred to as “Astellas”) announced today that companies have newly launched Cimzia® (certolizumab pegol) 200mg AutoClicks® for S.C. Injection in Japan as an additional formulation to the PEGylated*1 TNF-alpha (tumor necrosis factor-alpha) inhibitor Cimzia® 200mg Syringe for S.C. Injection for the treatment of rheumatoid arthritis (RA).

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®.

UCB Japan and Astellas believe that the AutoClicks® Prefilled Pen will be able to provide RA patients and medical professionals with a new treatment option and contribute further to treatment of the disease.

Product overview

Trade name	Cimzia® 200mg AutoClicks® for S.C. Injection
Generic name	Certolizumab Pegol (Genetical Recombination)
Indication	Treatment of rheumatoid arthritis (including inhibition of progression of bone structural damage)
Dosage and administration	Usually, for adults patients, Certolizumab pegol (recombinant) should be administered subcutaneously at 400mg at Weeks 0, 2, and 4, followed by 200mg every 2 weeks. For maintenance dosing, 400mg every 4 weeks s.c. can be considered.
NHI drug price	¥61,745
Date of approval	August 31, 2018
Date of listing in the NHI price	November 28, 2018
Date of initial marketing in Japan	November 28, 2018

Product photo



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 Good Grips® kitchen tools 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 Bepak

Bepak, 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 Bepak applies its proven know how and technologies to address the ever changing needs of the pharmaceutical industry, across multiple applications.

Bepak 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, Bepak 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.bepak.com>

About Cimzia®

Cimzia® is the world's first PEGylated anti-TNF-alpha (tumor necrosis factor alpha) antibody for the treatment of RA. It has a high affinity for TNF-alpha, which is involved in the onset and exacerbation of inflammatory diseases such as RA, and selectively inhibits the effects of TNF-alpha. It has an extended blood half-life due to PEG moiety attached to its Fc-free Fab region*² of the humanized antibody and is effective in the treatment of RA when injected subcutaneously every two weeks or once a month. In global clinical trials, co-therapy with Cimzia® and methotrexate (MTX) rapidly improved signs and symptoms of RA and continued to be effective during induction and maintenance therapy. Furthermore, Cimzia® prevented progression of structural joint destruction. In clinical trials conducted in Japan, Cimzia® reduced signs and symptoms in a rapid and sustained manner and prevented progression of joint destruction irrespective of MTX co-administration.

In addition to its efficacy and safety, its availability with AutoClicks® and a prefilled syringe shaped in a

form that facilitates its self-administration by RA patients at home when physicians permit it is expected to further contribute to improvement of symptoms in RA patients as well as their quality of life (QOL) and treatment adherence.

UCB and Astellas jointly develop and commercialize Cimzia® in Japan. Cimzia® was granted marketing authorization in Japan in December 2012 and was launched in March 2013. Under the terms of the agreement UCB will manufacture and supply the product for commercialization and Astellas will exclusively manage distribution and sales. UCB Japan and Astellas will work together to conduct promotion activities of the product in Japan.

About RA

RA is a progressive autoimmune disease associated with chronic inflammation of the joints. It generally affects the smaller joints in the body such as hands, wrists, feet and ankles. In addition to causing joint problems RA can sometimes affect other organs of the body such as the skin, eyes, lungs and blood vessels.¹ An estimated 600,000 - 1,000,000 people in Japan live with RA.² RA is more common in women than men and although it can occur at any age, it usually begins after the age of 40.¹

*1: PEGylation refers to the modification of an antibody with polyethylene glycol.

*2: The antibody is a Y-shaped molecule comprised of two antigen-recognizing Fab regions in the upper part and a complement-binding Fc region at the base

Reference

1. MayoClinic. Diseases and Conditions. Rheumatoid Arthritis. Accessed 17th November 2018 from <http://www.mayoclinic.org/diseases-conditions/rheumatoid-arthritis/basics/definition/con-20014868>
2. 「厚生科学審議会疾病対策部会 リウマチ等対策員会報告書」平成 30 年 11 月. Accessed 17th November 2018 from <https://www.mhlw.go.jp/content/10901000/000377563.pdf>

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 in immunology and neurology. With around 7,500 people in approximately 40 countries, the company generated revenue of € 4.5 billion in 2017. UCB is listed on Euronext Brussels (symbol: UCB). Established in 1988, UCB Japan markets a number of products. The anti-epileptic drug E Keppra®, Vimpat® and the TNF-α inhibitor Cimzia® will be a platform for further growth. As a biopharma leader, UCB Japan is dedicated to making a continuing contribution to the treatment and health of patients with severe diseases such as neurology and immunology/inflammatory diseases.

About Astellas

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. For more information, please visit our website at <https://www.astellas.com/en>

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