

Tillotts Pharma AG's parent company Zeria Pharmaceutical receives approval for Zentacort® 3mg capsules in Japan.

Zeria Pharmaceutical Co., Ltd. has received the approval for a new drug application for Zentacort 3mg capsules from the Ministry of Health, Labour and Welfare (MHLW) in Japan for the indication of the improvement of Crohn's Disease (CD). Following the acquisition of the worldwide rights to Entocort™ except the USA from AstraZeneca in July 2015, Zeria submitted the new drug application in October 2015 in Japan. Zentacort is sold as Entocort (generic name: budesonide) by Tillotts in more than 40 countries and recommended as first line therapy for treatment in CD in many international guidelines.

September 28, 2016. Zentacort was submitted in Japan after a special committee for the use of unapproved and off-label drugs with high unmet medical needs, operating under the Japanese MHLW, highlighted that there was a substantial need to make Zentacort available for the treatment in CD. AstraZeneca responded to the request from the Japanese MHLW and started the development of Zentacort in December 2010.

Zentacort is an enteric-coated sustained release formulation designated to release budesonide in the small intestine and the proximal colon. It is indicated for the treatment of mild to moderate active CD and, in some markets, ulcerative colitis (UC).

Zentacort is sold by Tillotts as Entocort in more than 40 countries for CD and, in some markets, ulcerative colitis (UC). CD and UC are types of inflammatory bowel diseases (IBD), one of the most prevalent gastrointestinal (GI) diseases, affecting over 2.2 million people in Europe and 5 million worldwide.

Tillotts CEO Thomas Tóth von Kiskér commented: "Tillotts is pleased that Zentacort will be introduced in Japan through Zeria. This approval further reinforces Tillotts' commitment as a leading specialist in the field of gastroenterology on a European and worldwide basis, offering patients a broad range of treatments for GI diseases".

Zeria expects that the approval of this new drug will make a significant contribution to treatment of mild to moderate CD in Japan. Sachiaki Ibe, Chairman of Tillotts and CEO of Zeria, declared: "We are extremely happy to introduce a product such as Zentacort in Japan, where the prevalence of CD is increasing, and to offer patients a well-established treatment."

About Tillotts

Tillotts Pharma AG, part of the Japanese Zeria Group, is a fast-growing specialty pharma company with over 250 employees in Switzerland and abroad. Tillotts is dedicated to the development, in/out-licensing and commercialisation of innovative pharmaceutical products for the digestive system. Tillotts successfully markets its own products Asacol™ and Entocort™, as well as in-licensed products, in over 65 countries through its affiliates within Europe and a network of gastroenterology-focused partners throughout the world.

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About Zeria

Zeria Pharmaceutical Co., Ltd., founded in 1955, based in Tokyo, Japan, focuses on R&D, manufacturing and sales of prescription drugs as well as OTC products. The company is listed on the First Section of Tokyo Stock Exchange (Stock code: 4559). Zeria holds a leading position within the gastroenterology field in Japan and operates internationally through a number of subsidiaries.

For more information about Zeria please visit www.zeria.co.jp.

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