SAMSUNG BIOEPIS

Samsung Bioepis' Marketing Authorization Application for SB5 Adalimumab Biosimilar Candidate Accepted for Review by the European Medicines Agency

- **If approved, SB5, a biosimilar candidate referencing Humira® (adalimumab), will be Samsung Bioepis' third anti-TNF-α biosimilar in Europe**
- **The Marketing Authorization Application for SB5 was based on a 52-week Phase III study which showed SB5's comparable efficacy and safety to Humira® among different treatment groups, including those who switched from Humira® to SB5.**

INCHEON, Korea – Jul 18, 2016 – Samsung Bioepis Co., Ltd. today announced that the European Medicines Agency (EMA) has accepted for review the company's Marketing Authorization Application (MAA) for SB5, a biosimilar candidate referencing Humira® (adalimumab).

SB5 is Samsung Bioepis' third anti-TNF-α biosimilar candidate submitted for review to the EMA, following Benepali® (etanercept) and Flixabi® (infliximab), both of which have since received European Commission approval in January 2016 and May 2016, respectively. If approved, the marketing and distribution of SB5 in Europe will be handled by Biogen.

"If approved, SB5 will join Benepali and Flixabi in Europe, which have already started to increase patient access to high-quality treatment options while driving down healthcare spending," said Christopher Hansung Ko, President & CEO of Samsung Bioepis. "We will continue to work hard to advance one of the industry's largest biosimilar pipelines, so that more patients can access affordable medicines without any compromise in the quality of treatment."

The MAA for SB5 was based on data derived from a 52-week Phase III study which randomized 544 patients with moderate to severe rheumatoid arthritis despite methotrexate therapy. 24-week results showed ACR20 response rate of 72.5% in the SB5 arm versus 72.0% in the adalimumab arm, while the safety profile of SB5 was comparable to adalimumab. At Week 24, 508 patients with rheumatoid arthritis were randomized in a 1:1 ratio to receive either SB5 or adalimumab 40 mg every other week via subcutaneous injection. 254 patients from SB5 continued to receive SB5 (SB5/SB5), 125 patients from adalimumab were transitioned to SB5 (adalimumab/SB5) and 129 patients from adalimumab continued to receive adalimumab (adalimumab/adalimumab). At Week 52, the efficacy, safety and immunogenicity profiles remained comparable between SB5/SB5, adalimumab/SB5 and adalimumab/adalimumab with ACR20 response rates of 76.9%, 81.1% and 71.2%, respectively. There were no treatment emergent issues or clinically relevant immunogenicity precipitated by switching. After transition up to Week 52, the incidence of anti-drug antibody was 15.7% in SB5/SB5, 16.8% in adalimumab/SB5 and 18.3% in adalimumab/adalimumab.

Samsung Bioepis Biosimilar Pipeline

Samsung Bioepis continues to advance a broad pipeline of 13 biosimilar candidates, which includes the following six first-wave candidates that cover the therapeutic areas of immunology, oncology and diabetes:

- SB4 biosimilar candidate referencing Enbrel® (etanercept)
- SB2 biosimilar candidate referencing Remicade® (infliximab)
- SB5 biosimilar candidate referencing Humira® (adalimumab)
- SB9 (MK-1293) biosimilar candidate referencing Lantus® (insulin glargine)
- SB3 biosimilar candidate referencing Herceptin® (trastuzumab)
- SB8 biosimilar candidate referencing Avastin® (bevacizumab)

Commercialization of Samsung Bioepis Biosimilars

Samsung Bioepis is responsible for the development and manufacture of all immunology and oncology biosimilar candidates in its pipeline, as well as global clinical trials and regulatory registration in all markets worldwide for these biosimilar candidates. Following approval, Samsung Bioepis biosimilar products are marketed and distributed by its commercialization partners, Merck and Biogen.

I. SB4 has received regulatory approval from the European Medicines Agency (EMA) and Korea's Ministry of Food and Drug Safety (MFDS), and is being marketed in Europe by Biogen as Benepali® and in Korea by MSD/Merck as BRENZYS®

II. SB2 has received regulatory approval from the EMA and MFDS, and is being marketed in Europe by Biogen as Flixabi® and in Korea by MSD/Merck as RENFLEXIS®.

Manufacturing of Samsung Bioepis Biosimilars

Samsung Bioepis and Biogen have a manufacturing partnership for anti-TNF-α biosimilars, which brings together Samsung Bioepis' technical leadership in manufacturing process development and Biogen's rich heritage and expertise in manufacturing biologics. Samsung Bioepis' biosimilars are manufactured in the same state-of-the-art drug substance facilities that have manufactured Biogen's biologic medicines.

About Samsung Bioepis Co., Ltd.

Established in 2012, Samsung Bioepis is a biopharmaceutical company committed to realizing healthcare that is accessible to everyone. Through innovations in product development and a firm commitment to quality, Samsung Bioepis aims to become the world's leading biopharmaceutical company. Samsung Bioepis continues to advance a broad pipeline of 13 biosimilar candidates that include six first-wave candidates that cover the therapeutic areas of immunology, oncology and diabetes. Samsung Bioepis is a joint venture between Samsung BioLogics and Biogen. For more information, please visit:
www.samsungbioepis.com.

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