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Samsung Bioepis' Biologics License Application for SB2 Infliximab Biosimilar Accepted by U.S. Food and Drug Administration

INCHEON, Korea--(BUSINESS WIRE/ME NewsWire)-- Samsung Bioepis Co., Ltd. today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the company's Biologics License Application (BLA) for SB2, a biosimilar candidate referencing Remicade® (infliximab), for the treatment of rheumatoid arthritis, Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis, and psoriasis.

This Smart News Release features multimedia. View the full release here: http://www.businesswire.com/news/home/20160523006086/en/

SB2 is the first Samsung Bioepis biosimilar candidate submitted for review in the United States (US). If approved, the marketing and distribution of SB2 in the US will be handled by Merck, in accordance with a commercialization agreement signed in 2013.

"At Samsung Bioepis, we are dedicated to bringing affordable, high-quality biologic medicines to patients across the United States. Already in other countries, our biosimilars have started to play an important role in increasing patient access to high-quality treatment options, while driving down healthcare expenditures. We hope to do the same in the US," said Christopher Hansung Ko, President & CEO of Samsung Bioepis. "We will continue our relentless drive for innovation and further advance one of the industry's largest biosimilar pipelines, so that more patients can have access to affordable medicines without compromising the quality of treatment."

Samsung Bioepis' BLA for SB2 was based on Phase 1 and Phase 3 clinical studies that tested the biosimilarity of SB2 to Remicade®. In a 54-week Phase 3 clinical study, SB2 showed comparable safety and equivalent efficacy to Remicade®, as evidenced in ACR20 response rate of 65.3% in the SB2 arm versus 69.2% in the Remicade® arm at week 54, fully supporting the 30-week study results of 64.1% and 66.0%, respectively. The SB2 study randomized 584 patients with moderate to severe rheumatoid arthritis despite methotrexate therapy across 73 sites in 11 countries.

Samsung Bioepis Biosimilar Pipeline

Samsung Bioepis continues to advance a broad pipeline of 13 biosimilar candidates, which includes the following six first-wave product 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 solely 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.

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 product 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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Contacts

Samsung Bioepis Co., Ltd.
MEDIA CONTACT:
Mingi Hyun, +82-32-455-6128
mingi.hyun@samsung.com
INVESTOR CONTACT:
Kwang Ryu, +82-32-455-6149
kwang1.ryu@samsung.com