BENEPALI®, the First Etanercept Biosimilar Referencing Enbrel®, Approved in the European Union

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Biogen will manufacture and commercialize BENEPALI in the EU

ZUG, Switzerland--(BUSINESS WIRE)--The joint venture between Biogen (NASDAQ:BIIB) and Samsung BioLogics, Samsung Bioepis, has been granted European Commission (EC) approval for BENEPALI® , an etanercept biosimilar referencing Enbrel®[i]. BENEPALI has been granted marketing authorization in the European Union (EU) for the treatment of adults with moderate to severe rheumatoid arthritis (RA), psoriatic arthritis, non-radiographic axial spondyloarthritis and plaque psoriasis. Biogen intends to make BENEPALI available for patients in the coming weeks.

BENEPALI is the first etanercept biosimilar referencing Enbrel to be approved in the EU, making it the first subcutaneous anti-TNF biosimilar available there. Anti-TNF's are the largest component of the EU biologics market, accounting for approximately $10 billion of all biologics sold there. [ii]

"The approval of BENEPALI is a significant step forward for patients and physicians, and an important milestone for Biogen as we bring to market the first product from our biosimilar pipeline," said Alpna Seth, Ph. D., Senior Vice President and Global Head of the Biosimilars Business Unit at Biogen. "As a biotechnology pioneer, Biogen is proud to translate our heritage and expertise in biologics to biosimilars. BENEPALI, as the first etanercept biosimilar referencing Enbrel approved in the EU, can help expand access to treatment options for people affected by chronic inflammatory conditions."

The EC approval was based on a robust preclinical and clinical data package submitted to the European Medicines Agency by Samsung Bioepis. The data in the preclinical submission leveraged sophisticated molecular analytics, technical development and manufacturing expertise. Confirmatory data from well-controlled, head-to-head Phase 1 and Phase 3 clinical trials compared BENEPALI to its reference product Enbrel.[iii, iv] The 52-week, double-blind, Phase 3 study randomized 596 patients with moderate to severe RA despite methotrexate therapy, across more than 70 sites in 10 countries to receive BENEPALI or Enbrel in a 1:1 ratio. Analysis of the primary endpoint showed that BENEPALI had equivalent efficacy to Enbrel, as shown by an ACR20 response at week 24 of 78.1% in the BENEPALI arm versus 80.3% in the Enbrel arm. Further analysis at 52 weeks confirmed comparable efficacy as shown by an ACR20 response of 80.8% in the BENEPALI arm versus 81.5% in the Enbrel arm. The safety profile of BENEPALI was comparable to that of Enbrel throughout the study.

"For more than 15 years anti-TNF therapies have revolutionized the care and outlook for patients living with chronic inflammatory diseases such as RA. However, access to these highly-effective treatments has been restricted by high costs," said Professor Peter Taylor, MA, FRCP, Ph. D., Norman Collisson Professor of Musculoskeletal Sciences, Kennedy Institute of Rheumatology, University of Oxford. "The development of biosimilar drugs is a welcome solution to help alleviate some challenges with access. The newly-approved treatment BENEPALI has similar quality, efficacy, and a comparable safety and immunogenicity profile to Enbrel."

About Biogen

Through cutting-edge science and medicine, Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological, autoimmune and rare diseases. Founded in 1978, Biogen is one of the world's oldest independent biotechnology companies and patients worldwide benefit from its leading multiple sclerosis and innovative hemophilia therapies. For more information, please visit www.biogen.com. Follow us on Twitter.

About Samsung Bioepis

Established in 2012, Samsung Bioepis is a biopharmaceutical company committed to increasing patient access to affordable, high-quality biologic medicines. Through innovations in product development and quality assurance, Samsung Bioepis aims to become the world's leading biopharmaceutical company. Samsung Bioepis is a joint venture between Samsung BioLogics and Biogen. For more information, please visit: www.samsungbioepis.com.

Biogen Safe Harbor

This press release includes forward-looking statements, including statements about the expected timing of availability of, and access to BENEPALI in the EU. These forward-looking statements may be accompanied by such words as "anticipate," "believe," "estimate," "expect," "forecast," "intend," "may," "plan," "will," and other words and terms of similar meaning. You should not place undue reliance on these statements. Drug development and commercialization is a lengthy and complex process, which involves a high degree of risk. Factors that could cause actual results to differ materially from our current expectations include; risks and delays associated with manufacturing processes; risks related to our dependence on third parties for the development and commercialization of biosimilars; general industry risks and competition; risks or unexpected concerns that may arise from additional data or analysis; risks of legal actions, regulatory scrutiny or other challenges to newly approved biosimilars products; inability to obtain adequate pricing or reimbursement of newly approved biosimilars products; and the risks of other unexpected hurdles. For more detailed information on the risks and uncertainties associated with our drug development and commercialization activities, please review the Risk Factors section of our most recent annual or quarterly report filed with the Securities and Exchange Commission. These statements are based on our current beliefs and expectations, and speak only as of the date of this press release. We do not undertake any obligation to publicly update any forward-looking statements.

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[i] Enbrel is a registered trademark of Wyeth LLC.

[ii] Extrapolated from global sales from GlobalData PMLive Top 50 Report

[iii] Vencovský J, et al. A Phase III, Randomized, Double-blind Clinical Study Comparing SB4, an Etanercept Biosimilar, with Etanercept Reference

Product (Enbrel®) in Patients with Moderate to Severe Rheumatoid Arthritis despite Methotrexate Therapy (52-week Results). Presented at the American College of Rheumatology, 9 November 2015, San Francisco, CA, USA. Samsung Bioepis data.

[iv] Lee Y J, et al. A Phase I Pharmacokinetic Study Comparing SB4, an Etanercept Biosimilar, and Etanercept Reference Product (Enbrel®) In Healthy Male Subjects. Presented at the European League Against Rheumatism, 13 June 2015, Rome, Italy. Samsung Bioepis data.

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