Biogen Announces Benepali™ (Etanercept) is the First Biosimilar of Enbrel® to Receive a Positive Opinion from CHMP

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Pending EC Approval, Biogen Would Commercialize Benepali in the EU

Positive Opinion is Based on a Robust Preclinical and Clinical Data Package Comparing Benepali to Enbrel

ZUG, Switzerland--(BUSINESS WIRE)--Biogen (NASDAQ:BIIB) today announced further progress as part of its commitment to biosimilars. Samsung Bioepis, the joint venture between Samsung Biologics and Biogen, has received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for the marketing authorization of Benepali ™ (etanercept). Previously known as SB4, Benepali is a biosimilar candidate to the reference product Enbrel®[1]. The positive opinion will now be referred to the European Commission (EC), which grants marketing authorization for medicines in the European Union (EU). If approved, Benepali could be the first biosimilar of Enbrel granted approval in the EU, as well as the first subcutaneous anti-TNF biosimilar there.

“The positive CHMP recommendation for Benepali is a great step forward for patients, physicians and payers in Europe. Biosimilars have the potential to help improve access to important biologic treatments for those who need them most,” said Alpna Seth, vice president and global head of the biosimilars business unit at Biogen. “As a biotechnology leader with more than 35 years of experience in developing, manufacturing and commercializing advanced biologics, we look forward to bringing an array of anti-TNF biosimilar medicines to patients across Europe.”

The CHMP’s positive opinion was based on a robust preclinical and clinical data package submitted to the EMA by Samsung Bioepis. The data in the preclinical submission leveraged sophisticated molecular analytics, technical development, and manufacturing expertise, together with confirmatory data from head-to-head Phase 1 and Phase 3 clinical trials of Benepali compared to its reference product Enbrel [2,3]. The 52-week, double-blind, Phase 3 study randomized 596 patients with moderate to severe rheumatoid arthritis (RA) despite methotrexate therapy across 70 sites in 10 countries to receive Benepali or Enbrel in a 1:1 ratio. Results showed an ACR20 response rate 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.

About Benepali ™

Benepali (etanercept), formerly known as SB4 in Europe, is an investigational treatment developed as a biosimilar to the reference product Enbrel. Pending EC review and approval, Benepali could be indicated for the treatment of moderate to severe RA, psoriatic arthritis, non-radiographic axial spondyloarthritis, and plaque psoriasis.

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

Samsung Bioepis was established in 2012 as part of the Samsung group. It is a joint venture between Samsung Biologics and Biogen. Its mission is to produce affordable, high-quality biopharmaceutical products for patients in need. Samsung Bioepis aims to be a world-leading biopharmaceutical company leveraging a heritage of innovation and advanced technologies. Please visit www.samsungbioepis.com for more information.

Biogen Safe Harbor

This press release includes forward-looking statements, including statements about the potential to bring anti-TNF biosimilar product candidates to market. 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 the risk that unexpected concerns may arise from additional data or analysis; the risk that regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our product candidates; risks associated with manufacturing processes; risks related to our dependence on third parties for the development and commercialization of biosimilars; and the risk that we encounter 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.

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

[2] 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.

[3] 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.

Contact:

Biogen Media:
Shannon Altimari, +41 41 392 1677
publicaffairs.EU@biogen.com
or
Biogen Investors:
Mike Hencke, +1 781-464-2442
IR@biogen.com