SB5, An Adalimumab Biosimilar Referencing Humira®, Accepted for Review by European Medicines Agency

July 17, 2016

Submission from Samsung Bioepis includes data from clinical trials that demonstrate equivalence of the proposed biosimilar to the reference product Humira

The approval of SB5 could make Biogen the first company to commercialize three anti-TNF biosimilar therapies in Europe

ZUG, Switzerland--(BUSINESS WIRE)--The Marketing Authorization Application (MAA) for SB5, an adalimumab biosimilar candidate referencing Humira®[1], has been accepted for review by the European Medicines Agency (EMA). The MAA for SB5 is the third anti-TNF biosimilar candidate to be submitted to the EMA by Samsung Bioepis, the joint venture between Samsung BioLogics and Biogen (Nasdaq: BIIB). Earlier this year, the European Commission approved BENEPALI® (etanercept), a biosimilar referencing Enbrel®[2], and FLIXABI® (infliximab), a biosimilar referencing Remicade®[3].

Humira is approved in the European Union (EU) for use in moderate to severe rheumatoid arthritis (RA), ankylosing spondylitis, moderate to severe plaque psoriasis, active and progressive psoriatic arthritis, moderate to severely active Crohn's disease, and moderate to severely active ulcerative colitis.

“The submission of SB5 by Samsung Bioepis reflects the joint goal of the partners to take the lead in expanding access to high-quality biologic therapies for those living with chronic inflammatory disorders,” said Alpna Seth, Ph.D., Senior Vice President and Global Head of the Biosimilars Business Unit at Biogen. “At an estimated $4Bn a year,[i] Humira is among the EU’s largest single drug expenditures, but access still remains variable in many markets. If SB5 is approved, we will have the potential to make a substantial impact by bridging this access gap for patients while supporting the sustainability of healthcare systems.”

The MAA is based on a robust preclinical and clinical data package comparing SB5 with Humira. The clinical data include results from two head-to-head studies – a Phase I study in healthy volunteers that demonstrated pharmacokinetic bioequivalence to Humira[ii] and a Phase III, randomized, double-blind, multicenter study, in which SB5 demonstrated comparable efficacy, safety, and immunogenicity to Humira in patients with RA.[iii] The primary endpoint of the Phase III study, the ACR20 score response at Week 24, was met, demonstrating equivalent efficacy to Humira. Secondary endpoints demonstrated that SB5 has a comparable safety and immunogenicity profile to Humira.[iii]

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.

Biogen Safe Harbor
This press release includes forward-looking statements, including statements about the potential indications for SB5, and the approval of SB5 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: the risk that unexpected concerns may arise from additional data or analysis, or regulatory authorities may require additional data or information or further studies, or may fail to approve, or refuse to approve, or may delay approval of our biosimilar drug candidates risks related to our dependence on third parties for the development and commercialization of biosimilars; risks of legal actions, regulatory scrutiny or other challenges to biosimilars; 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.

[1] Humira is a registered trademark of AbbVie.

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

[3] Remicade is a registered trademark of Janssen Biotech, Inc.

[i] Extrapolated from global sales from Global Data PMLive Top 50 Report.

[ii] Shin D, Kim Y, Kim HS, et al. A Phase I Pharmacokinetic Study Comparing SB5, An Adalimumab Biosimilar, And Adalimumab Reference Product (Humira®) in Healthy Subjects. Ann Rheum Dis. 2015; 74 (suppl 2:1265).

[iii] Weinblatt ME, Baranauskaite A, Niebrzydowski J, et al. A Phase III, Randomized, Double-Blind Clinical Study Comparing SB5, an Adalimumab Biosimilar, with Adalimumab Reference Product (Humira®) in Patients with Moderate to Severe Rheumatoid Arthritis Despite Methotrexate Therapy (24-week results) [abstract]. Arthritis Rheumatol. 2015; 67 (suppl 10).

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