FLIXABI®, an Infliximab Biosimilar Candidate Referencing Remicade®, Receives Positive CHMP Opinion

April 1, 2016

FLIXABI to be the second anti-TNF biosimilar commercialized and manufactured by Biogen in the EU

ZUG, Switzerland--(BUSINESS WIRE)--The Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion for the marketing authorization of FLIXABI® (infliximab). Previously known as SB2, FLIXABI is an infliximab biosimilar candidate referencing Remicade®[i], which was developed by Samsung Bioepis, the joint venture between Samsung BioLogics and Biogen (NASDAQ: BIIB). 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 by the EC, FLIXABI could be prescribed in the same indications as Remicade. This includes treatment of adults with rheumatoid arthritis (RA), Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis, and psoriasis. FLIXABI could also be used in patients six to 17 years old with severe, active Crohn's disease or severely active ulcerative colitis.

The positive CHMP opinion comes shortly after marketing authorization was granted for BENEPALI® (etanercept), a biosimilar referencing Enbrel®[ii]. Both FLIXABI and BENEPALI are anti-TNF therapies, a treatment class which accounts for the largest prescribed segment of the global biologics market.

"The positive CHMP opinion for FLIXABI marks another important milestone for our biosimilars business this year. We are excited to harness this positive momentum as we prepare to bring our second biosimilar treatment to patients in the EU," said Alpna Seth, Ph.D., Senior Vice President and Global Head of the Biosimilars Business Unit at Biogen. "Biogen is building upon its deep expertise in manufacturing and commercializing biologics for immunological conditions by bringing forth these important therapies. Biosimilars will increase choice and access for patients in the EU, while providing potential cost savings to healthcare systems."

The CHMP's positive opinion was based on a robust preclinical and clinical data package submitted to the European Medicines Agency by Samsung Bioepis. Data in the preclinical submission established similarity and comparability between FLIXABI and its reference product, Remicade. The clinical submission included confirmatory data from head-to-head Phase 1 and Phase 3 clinical trials comparing FLIXABI to the reference product.[iii,iv]

The 54-week, double-blind, Phase 3 study was conducted in patients with moderate to severe RA despite methotrexate therapy. The primary end point was the American College of Rheumatology 20% (ACR20) response at week 30 in the per-protocol set (PPS). ACR20 evaluates effectiveness of RA treatments by measuring improvement in physical and clinical measures, including tender and swollen joint counts, a key symptom of RA. The primary end point for the study was met, with data showing patients taking FLIXABI had an equivalent ACR20 response and a comparable safety profile to those taking Remicade.[iv]

- A total of 584 patients were randomized in a 1:1 ratio to either FLIXABI (N=291, 290 analyzed) or Remicade (N=293)[iv]
- The ACR20 response rate at week 30 in the PPS showed equivalence of FLIXABI to Remicade: 64.1% vs. 66.0%, respectively (adjusted difference −1.88%; 95% CI −10.26% to 6.51%). The ACR20 response rate at week 54 in the PPS confirmed equivalent efficacy, with results showing 65.3% vs. 69.2%, respectively (adjusted difference 3.07%; 95% CI: 12.00% to 5.86%)[iv]
- ACR20 response in the full analysis set at week 30 and week 54 also showed equivalence of FLIXABI to Remicade: 55.5% vs. 59.0%, respectively (adjusted difference 2.95%; 95% CI: 10.88% to 4.97%) at week 30 and 50.7% vs. 52.6%, respectively (adjusted difference 1.15%; 95% CI: 9.16% to 6.86%) at week 54[iv]
- FLIXABI was well tolerated with comparable safety, pharmacokinetics and immunogenicity to Remicade[iv]

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 FLIXABI, and the potential approval of FLIXABI 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.

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

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

[iii] Shin D et al. A Randomized, Phase I Pharmacokinetic Study Comparing SB2 and Infliximab Reference Product (Remicade®) in Healthy Subjects. BioDrugs. 2015;29(6):381-8.

[iv] Choe J-Y, et al. A Randomized, Double-Blind, Phase III Study Comparing SB2, an Infliximab Biosimilar, to the Infliximab Reference Product (Remicade®) in Patients with Moderate to Severe Rheumatoid Arthritis Despite Methotrexate Therapy: 54-Week Results. Presented at The ACR/ARHP Annual Meeting, 9 November 2015, San Francisco, USA.

Contact:

BIOGEN US MEDIA CONTACT:
Jason Glashow, +1 781-464-3260
public.affairs@biogen.com
or
BIOGEN EU MEDIA CONTACT:
Shannon Altimari, +41 41 392 1677
publicaffairs.EU@biogen.com
or
BIOGEN INVESTOR CONTACT:
Mike Hencke, +1 781-464-2442
IR@biogen.com