



## FLIXABI®, Biogen's Infliximab Biosimilar Referencing Remicade®, Approved in the European Union

May 30, 2016

*Biogen to manufacture and commercialize FLIXABI, the company's second anti-TNF biosimilar therapy in the EU*

ZUG, Switzerland--(BUSINESS WIRE)--The European Commission (EC) today granted marketing authorization in the European Union (EU) for FLIXABI®, an infliximab biosimilar referencing Remicade®<sup>i</sup>. FLIXABI was developed by Samsung Bioepis, the joint venture between Samsung BioLogics and Biogen (NASDAQ: BIIB). FLIXABI is indicated for the treatment of adults with rheumatoid arthritis (RA), Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis, and psoriasis. Additionally, FLIXABI can be used in patients 6 to 17 years old with severe, active Crohn's disease or severely active ulcerative colitis.

FLIXABI will be the second anti-TNF biosimilar to be manufactured and commercialized by Biogen in the EU. Earlier this year, Samsung Bioepis received approval for BENEPALI® (etanercept), a biosimilar referencing Enbrel®<sup>ii</sup>. Biogen has since launched BENEPALI in several countries across the EU. At an estimated \$10Bn a year,<sup>iii</sup> anti-TNF therapies are among the EU's largest drug expenditures.<sup>iv</sup> BENEPALI and FLIXABI will offer physicians alternatives that will drive meaningful savings across the EU.

"The approval of FLIXABI marks a major step forward for both Samsung Bioepis and Biogen. It expands our anti-TNF portfolio and furthers Biogen's commitment to commercializing biosimilars of advanced biologics, while expanding cost-effective treatment options for patients living with chronic inflammatory conditions such as Crohn's disease and ulcerative colitis," said Alpna Seth, Ph.D., Senior Vice President and Global Head of the Biosimilars Business Unit at Biogen. "We are delighted to be the first company to bring two anti-TNF biosimilars to patients and physicians across Europe."

As part of the submission, Samsung Bioepis provided a robust preclinical and clinical data package from head-to-head Phase 1 and Phase 3 clinical trials comparing FLIXABI with the reference product Remicade.<sup>v,vi</sup> Following biosimilar approval guidelines from the European Medicines Agency, the Phase 3 clinical trial for FLIXABI was performed to confirm equivalent efficacy, and to compare safety and immunogenicity with Remicade. 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).<sup>vii</sup> The primary end point for the study was met, with data showing that patients taking FLIXABI had an equivalent ACR20 response and a comparable safety profile to those taking Remicade.<sup>vi</sup>

- A total of 584 patients were randomized in a 1:1 ratio to either FLIXABI (N=291, 290 analyzed) or Remicade (N=293)<sup>vi</sup>
- 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%)<sup>vi,viii</sup>
- 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<sup>vi,viii</sup>
- FLIXABI was well tolerated, with comparable safety, pharmacokinetics and immunogenicity to Remicade<sup>vi,viii</sup>

### 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](http://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 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.

<sup>i</sup> Remicade is a registered trademark of Janssen Biotech, Inc.

ii Enbrel is a registered trademark of Wyeth LLC.

iii Extrapolated from global sales from GlobalData PMLive Top 50 Report.

iv IMS MIDAS, Q2 2014, Rx.

v 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.

vi 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. *Ann Rheum Dis*. 2015;0:1–7. doi:10.1136/annrheumdis-2015-207764.

vii 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.

viii 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.

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