New Data Presented at the Annual European Congress of Rheumatology (EULAR 2016) Demonstrate Safety and Efficacy of Biogen's Anti-TNF Biosimilars Portfolio

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Data confirm safety and efficacy of switching from Enbrel ® and Remicade ® to BENEPALI ® and FLIXABI ® respectively

ZUG, Switzerland--(BUSINESS WIRE)--Data demonstrating long-term comparable efficacy, safety and immunogenicity of BENEPALI® (etanercept) and FLIXABI® (infliximab) were presented by Samsung Bioepis, the joint venture between Samsung BioLogics and Biogen (NASDAQ: BIIB), at the Annual European Congress of Rheumatology *(*EULAR 2016*)*, held 8–11 June in London, UK. Results showed that in patients who were switched from the reference product Enbrel[i] to BENEPALI, there were no treatment-emergent safety or immunogenicity issues, and efficacy was sustained for up to two years.[ii] Comparable safety, immunogenicity and sustained efficacy were also demonstrated in patients who were switched from Remicade[iii] to FLIXABI, compared with those who continued on Remicade.[iv] BENEPALI and FLIXABI were both approved by the European Commission (EC) earlier this year and are commercialized in Europe by Biogen.

Additional data presented at the congress include results from Phase I and Phase III studies of SB5, an adalimumab biosimilar candidate referencing Humira®.[v] Results showed sustained and comparable efficacy, and comparable safety and immunogenicity profiles over 52 weeks in patients who transitioned from Humira to SB5 at Week 24, compared with patients who continued to receive the reference product[vi] and those who continued on SB5.

"Biologics have benefitted a large number of patients, effectively revolutionizing the treatment of rheumatic diseases. Biosimilars can help more patients gain access and benefit from biologic therapies, while providing cost savings to healthcare systems and supporting future healthcare innovation," said Alpna Seth, Ph.D., Senior Vice President and Global Head of the Biosimilars Business Unit at Biogen. "The data presented by our partners Samsung Bioepis at EULAR reinforce the comparable safety and efficacy of our anti-TNF biosimilars portfolio in patients living with chronic inflammatory conditions, including rheumatoid arthritis."

"The integration of biosimilars in routine clinical practice is a crucial step to help patients' access disease modifying biologic therapies they can significantly benefit from," said Professor John Isaacs, Director of the Institute of Cellular Medicine at Newcastle University and consultant rheumatologist at the Freeman Hospital. "Patient safety is of the utmost importance, and we are beginning to see a solid bank of data that, together with real-world evidence, will further establish the role of biosimilars."

The posters presented at the Annual European Congress of Rheumatology (EULAR 2016) by Samsung Bioepis include:

BENEPALI:

- *Emery P, et al. Long-Term Safety and Efficacy of SB4 (Etanercept Biosimilar) in Patients With Rheumatoid Arthritis: Comparison Between Continuing SB4 and Switching From Etanercept Reference Product to SB4* [THU0150] – Thursday, June 9, 2016, 11.45am BST, Poster Area

FLIXABI:

- *Smolen JS, et al. Comparable Safety and Immunogenicity and Sustained Efficacy After Transition to SB2 (An Infliximab Biosimilar) vs Ongoing Infliximab Reference Product in Patients With Rheumatoid Arthritis: Results of Phase III Transition Study* [FRI0162] – Friday, June 10, 2016, 11.50am BST, Poster Area
- *Choe J-Y, et al. Efficacy and Safety Analysis by Overall Anti-drug Antibody Results up to Week 30 in Patients with Rheumatoid Arthritis Treated with SB2 (an Infliximab Biosimilar) or Infliximab Reference Product in Phase III study* [THU0140] – Thursday, June 9, 2016, 11.45am BST, Poster Area
- *Durez P, et al. The 54-week Results of Interferon-γ Release Assay in A Phase III Study Comparing SB2, An Infliximab Biosimilar, to Infliximab Reference Product in Patients with Rheumatoid Arthritis* [THU0149] – Thursday, June 9, 2016, 11.45am BST, Poster Area

SB5 (adalimumab):

- *Weinblatt M, et al. Sustained Efficacy and Comparable Safety and Immunogenicity After Transition to SB5 (an Adalimumab Biosimilar) vs Continuation of the Adalimumab Reference Product in Patients with Rheumatoid Arthritis: Result of Phase III study* [FRI0161] – Friday, June 10, 2016, 11.50am BST, Poster Area
- *Kay J, et al. Secondary Efficacy Results up to Week 24 from a Phase III Study Comparing SB5 (an Adalimumab Biosimilar) with Adalimumab Reference Product in Patients with Moderate to Severe Rheumatoid Arthritis Despite Methotrexate Therapy* [THU0138] – Thursday, June 9, 2016, 11.45am BST, Poster Area
- *Genovese MC, et al. Impact of Anti-Drug Antibodies on Efficacy and Safety up to Week 24 From a Phase III Study Comparing SB5 (an Adalimumab Biosimilar) With Adalimumab Reference Product in Patients With Moderate to Severe*

Rheumatoid Arthritis Despite Methotrexate Therapy [THU0146] – Thursday, June 9, 2016, 11.45am BST, Poster Area

- *A Phase I Pharmacokinetic Study Comparing Pre-Filled Pen and Pre-Filled Syringe of SB5, an Adalimumab Biosimilar in Healthy Subjects* [Abstract only]

About BENEPALI

BENEPALI is an etanercept biosimilar to the reference product Enbrel®[7]. BENEPALI is approved in Europe for the treatment of adults with moderate to severe RA, psoriatic arthritis, non-radiographic axial spondyloarthritis and plaque psoriasis. BENEPALI is currently available in five European countries, namely, the UK, Germany, Norway, Sweden and the Netherlands.

About FLIXABI

FLIXABI is an infliximab biosimilar to the reference product Remicade®[8]. FLIXABI is approved in Europe for the treatment of adults with RA, Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis or psoriasis. FLIXABI can also be used in patients 6–17 years old with severe, active Crohn's disease or severely active ulcerative colitis.

About SB5

SB5 is an investigational treatment being developed as a biosimilar to the reference product Humira®.

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 benefits of our products and programs and expected timing of results from clinical trials. 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.

References

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

[ii] Emery P, et al. Long-term Safety and Efficacy of SB4 (Etanercept Biosimilar) in Patients with Rheumatoid Arthritis: Comparison Between Continuing SB4 and Switching from Etanercept Reference Product to SB4. Poster presented at the European League Against Rheumatism (EULAR) Annual Congress, 9 June 2016, London UK. Samsung Bioepis data

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

[iv] Smolen JS, et al. Comparable Safety and Immunogenicity and Sustained Efficacy after Transition to SB2 (an Infliximab Biosimilar) vs Ongoing Infliximab Reference Product in Patients with Rheumatoid Arthritis: Results of Phase III Transition Study. Poster presented at the European League Against Rheumatism (EULAR) Annual Congress, 9 June 2016, London UK. Samsung Bioepis data.

[v] Humira is a registered trademark of Abbvie Biotechnology Ltd.

[vi] Weinblatt M, et al. Sustained Efficacy and Comparable Safety and Immunogenicity after Transition to SB5 (an Adalimumab Biosimilar) vs Continuation of the Adalimumab Reference Product in Patients with Rheumatoid Arthritis: Results of Phase III Study. Poster presented at the European League Against Rheumatism (EULAR) Annual Congress, 9 June 2016, London UK. Samsung Bioepis data

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