IMRALDI®, Biogen's Adalimumab Biosimilar Referencing Humira®, is Approved in the European Union

August 24, 2017

Biogen becomes the first company with approved biosimilars for the three most prescribed anti-TNF biologic treatments in Europe.

ZUG, Switzerland--(BUSINESS WIRE)--The European Commission (EC) granted a marketing authorization for IMRALDI® (also known as SB5), an adalimumab biosimilar referencing Humira®.[1]

IMRALDI has been developed by Samsung Bioepis, a joint venture between Samsung BioLogics and Biogen (NASDAQ, BIIB) and is approved for the treatment of rheumatoid arthritis (RA), juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, pediatric plaque psoriasis, adult and adolescent hidradenitis suppurativa, Crohn's disease, pediatric Crohn's disease, ulcerative colitis and uveitis.

IMRALDI is the third anti-TNF biosimilar from Biogen to receive a marketing authorization in the European Union (EU) following the approval in 2016 of BENEPALI® (etanercept), a biosimilar referencing Enbrel®,[2] and FLIXABI® (infliximab), a biosimilar referencing Remicade®.[3] Anti-TNF therapies represent some of the EU's largest drug expenditures, costing an estimated $9 billion (€8 billion) each year from 2011 to 2014. [4,5] Introducing biosimilars of the top three anti-TNF therapies in Europe could lead to estimated potential savings of up to $11.44 billion (€9.69 billion), between the patent expiry date of each reference product and 2020.[5,6] With the approval of IMRALDI, Biogen has become the first company to have approved biosimilars for all three of these therapies.

"Today's decision marks another positive step in transforming the lives of people with chronic autoimmune conditions," said Jean-Paul Kress, EVP International and Head of Global Therapeutic Operations, Biogen. "As the number of approved biosimilars continues to grow, so does the anticipated potential to increase physician choice and patient access to biologics."

The EC approval was based on a robust preclinical and clinical data package comparing IMRALDI 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[7] and a 52 week Phase III, randomized, double-blind, multicenter study, in which IMRALDI demonstrated comparable efficacy and comparable safety and immunogenicity to Humira in patients with moderate to severe RA despite methotrexate therapy.[8,9] The primary endpoint of the Phase III study, the American College of Rheumatology 20% (ACR20) response at Week 24, was met, demonstrating equivalent efficacy to Humira (ACR20 response rate was 72.5% in the IMRALDI group versus 72.0% in the Humira group).[8] Between Week 24 and Week 52, in 125 patients who were switched from Humira to IMRALDI, efficacy, safety, and immunogenicity profiles were found to be comparable to those in patients who remained on Humira (129) or IMRALDI (254) during the transition period.[9]

About Biogen
Through cutting-edge science and medicine, Biogen discovers, develops and delivers innovative therapies worldwide for people living with serious neurological and neurodegenerative diseases. Founded in 1978, Biogen is a pioneer in biotechnology and today the Company has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first and only approved treatment for spinal muscular atrophy, and is at the forefront of neurology research for conditions including Alzheimer's disease, Parkinson's disease and amyotrophic lateral sclerosis. Biogen also manufactures and commercializes biosimilars of advanced biologics. For more information, please visit www.biogen.com. Follow us on social media – Twitter, LinkedIn, Facebook, YouTube.

Biogen Safe Harbor
This press release includes forward-looking statements, including statements about the indications from approval and anticipated access to IMRALDI in the EU, and the potential cost savings from the availability of IMRALDI and other biosimilar anti-TNF therapies 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 which could prevent the commercial launch of a product or delay it for many years; 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

[1] Humira® is a registered trademark of AbbVie Biotechnology Ltd.

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

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

[4] Extrapolated from global sales from Global Data PMLive Top 50 report, available at: http://www.pmlive.com/top_pharma_list/Top_50_pharmaceutical_products_by_global_sales. Accessed August 2017

[5] Currency exchange rates (rounded). Available at: www.xe.com. Accessed August 2017.

[6] Psachoulia E, et al. Potential impact of the biosimilars introduction of 3 anti-TNFs in the European market. Value Health 2017;20(5);A143.

[7] Shin D, 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.
[8] Weinblatt M, 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).
[9] Weinblatt M, et al. FRI0161 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. Annals of the Rheumatic Diseases 2016;75:487.

Contact:

BIOGEN EU MEDIA CONTACT:
Ryan Furby, +41 413 920 652
publicaffairs.EU@biogen.com
or
BIOGEN INVESTOR CONTACT:
Mike Hencke, +1 781-464-2442
IR@biogen.com