Biogen's IMRALDI®, an Adalimumab Biosimilar Candidate Referencing Humira®, Granted Positive Opinion by Committee for Medicinal Products for Human Use

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If approved, IMRALDI would be the third anti-TNF biosimilar in Biogen's portfolio in Europe, helping to expand affordable therapy options and increase access for patients with chronic anti-inflammatory disorders such as rheumatoid arthritis

Humira is the number-one prescribed biologic therapy in the world and accounts for almost half of anti-TNF healthcare expenditures in Europe

ZUG, Switzerland--(BUSINESS WIRE)--The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion for IMRALDI® (also known as SB5), an adalimumab biosimilar candidate referencing Humira®.[1] The positive opinion will now be referred to the European Commission (EC), which grants marketing authorization for medicines in the European Union (EU). IMRALDI marks the third anti-TNF candidate to be submitted to the EMA by Samsung Bioepis, the joint venture between Samsung BioLogics and Biogen.

If approved by the EC, IMRALDI would be approved for the treatment of rheumatoid arthritis, axial spondyloarthritis, ankylosing spondylitis, plaque psoriasis, psoriatic arthritis, Crohn's disease, ulcerative colitis, polyarticular juvenile idiopathic arthritis, active enthesitis-related arthritis, hidradenitis suppurativa and non-infectious uveitis.

Today, the anti-TNF market alone accounts for an estimated $9 billion of healthcare expenditures in Europe,[2] of which Humira accounts for $4 billion.[2] Global sales estimates for Humira stand at $16 billion in 2017, making it the number-one prescribed biologic therapy in the world.[3] Earlier this year, data were unveiled at the ISPOR 22nd Annual Meeting in Boston showing that biosimilar introduction of the top-three anti-TNF therapies in Europe could result in savings of $11.44 billion by 2020.[4] Of these savings, $3.18 billion could be attributed to prescribing an adalimumab biosimilar referencing Humira, despite only being approved near the end of the study period.[4]

"If IMRALDI receives approval, Biogen will be the first company to have approved biosimilars of the three most prescribed anti-TNF biologic treatments in Europe," said Alpna Seth, Ph.D., Senior Vice President and Global Head of the Biosimilars Business Unit at Biogen. "This portfolio expansion is in line with our mission to increase access to biologics that have transformed the treatment of chronic autoimmune conditions like rheumatoid arthritis. Being able to provide this range of anti-TNF treatment alternatives bolsters our leadership position and underscores our commitment to expanding physician choice, while supporting the sustainability of healthcare systems."

The positive opinion is 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[5] and a Phase III, randomized, double-blind, multicenter study, in which IMRALDI demonstrated equivalent efficacy and comparable safety and immunogenicity to Humira in patients with RA.[6] 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.[6] Secondary endpoints demonstrated that IMRALDI has a comparable safety and immunogenicity profile to Humira.[6]

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 potential indications for IMRALDI, and the potential approval of IMRALDI 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.

References

[1] Humira® is a registered trademark of AbbVie Biotechnology Ltd.
[2] Extrapolated from global sales from Global Data PMLive Top 50 Report.
[3] Gibney M. FiercePharma special report: The top 20 drugs in 2020 – worldwide sales (1. Humira).
[4] Psachoulia et al. Potential impact of the biosimilars introduction of 3 anti-TNFs in the European market. Value Health 2017, May; 20(5); A143.
[5] 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).
6 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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