Biogen and Samsung Bioepis Announce European Launch of IMRALDI™ (adalimumab), Solidifying Leadership in European Anti-TNF Market

IMRALDI™ (adalimumab), a biosimilar referencing HUMIRA® [1], is the third anti-TNF biosimilar developed by Biogen across Europe, following BENEPALI™ (etanercept) and FLIXABITM (infliximab).

Biogen and Samsung Bioepis were the first in Europe to receive approvals for biosimilars referencing the three most prescribed anti-TNF medicines in Europe.

CAMBRIDGE, MASSACHUSETTS, U.S. and INCHEON, KOREA – October 17, 2018 – Biogen (Nasdaq: BIIB) and Samsung Bioepis Co., Ltd. today announced the European launch of IMRALDI™ (adalimumab), a biosimilar referencing HUMIRA®. Starting today, IMRALDI™ will begin launching in major markets across Europe.

The launch of IMRALDI™ marks a significant milestone for Biogen and Samsung Bioepis, as the adalimumab product is the third anti-TNF biosimilar developed by Samsung Bioepis to be commercialized by Biogen across Europe. BENEPALI™ (etanercept) and FLIXABITM (infliximab) were approved in 2016, and have approximately 100,000 patients currently under treatment with more than 6 million doses administered across 25 and 14 countries, respectively [2].

“We look forward to increasing patient access to this important medicine by leveraging our industry-leading position in the European anti-TNF market,” said Ian Henshaw, Head of Biogen’s Biosimilars Unit.

“The launch of IMRALDI marks what we believe to be a landmark moment for Biogen and Samsung Bioepis and for European healthcare systems. We hope IMRALDI will play an important role widening choice and increasing competition in one of the most high-value areas of the biopharmaceuticals market,” said Sang-Jin Pak, Chief Operating Officer, Samsung Bioepis. “In just six years, Samsung Bioepis has successfully developed the industry’s leading portfolio of anti-TNF biosimilars with a strong pipeline of further biosimilar candidates currently under development.”

“We are proud of our collaboration with Biogen, which brings together the development expertise of Samsung Bioepis with the commercial excellence of Biogen for the benefit of patients across Europe.”

The European Commission (EC) approved IMRALDI™ in August 2017 for the treatment of rheumatoid arthritis (RA), juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatic plaque psoriasis, adult and adolescent hidradenitis suppurativa, Crohn’s disease, paediatric Crohn’s disease, ulcerative colitis and uveitis [3].

The EC approval was based on data derived from a randomized, double-blind 52-week Phase 3 study, in which 544 patients with moderate to severe rheumatoid arthritis despite methotrexate (MTX) therapy were randomized to receive either SB5 or the adalimumab reference product (ADL). At Week 24, the ACR20 response rate was 72.4% in the SB5 group versus 72.2% in the ADL group. The safety profile of SB5 was comparable to ADL up to Week 24. At Week 24, 254 patients receiving ADL were re-randomized in a 1:1 ratio to continue on ADL or transitioned to SB5, and 254 patients receiving SB5 continued to receive SB5. Up to Week 52, the efficacy, safety and immunogenicity profiles remained comparable between all three treatment groups. There were no treatment emergent issues or clinically relevant immunogenicity precipitated by alternating subjects between treatments [4, 5].

About Biogen

At Biogen, our mission is clear: we are pioneers in neuroscience. Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases. One of the world’s first global biotechnology companies, Biogen was founded in 1978 by Charles Weissmann, Heinz Schaller, Kenneth Murray and Nobel Prize winners Walter Gilbert and Phillip Sharp, and today has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first and only approved treatment for spinal muscular atrophy and is focused on advancing neuroscience research programs in Alzheimer’s disease and dementia, multiple sclerosis and neuroimmunology, movement disorders, neuromuscular disorders, pain, ophthalmology, neuropsychiatry and acute neurology. Biogen also manufactures and commercializes biosimilars of advanced biologics.

We routinely post information that may be important to investors on our website at www.biogen.com. To learn more, please visit www.biogen.com and follow us on social media – Twitter, LinkedIn, Facebook, YouTube.
About Samsung Bioepis Co., Ltd.

Established in 2012, Samsung Bioepis is a biopharmaceutical company committed to realizing healthcare that is accessible to everyone. Through innovations in product development and a firm commitment to quality, Samsung Bioepis aims to become the world’s leading biopharmaceutical company. Samsung Bioepis continues to advance a broad pipeline of biosimilar candidates that cover a spectrum of therapeutic areas, including immunology, oncology and ophthalmology. Samsung Bioepis is a joint venture between Samsung BioLogics and Biogen. For more information, please visit: www.samsungbioepis.com.

Biogen Safe Harbor

This press release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, about the potential benefits, safety and efficacy of IMRALDI; the results of certain Phase 3 studies of IMRALDI; the potential of Biogen’s commercial business, including IMRALDI, BENEPALI and FLIXABII; risks and uncertainties associated with drug development and commercialization, including the commercialization of IMRALDI; and market acceptance of biosimilars and related healthcare system matters. These statements may be identified by words such as “aim,” “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “plan,” “possible,” “potential,” “will” and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including uncertainty of success in commercialization of IMRALDI, which may be impacted by, among other things, the level of preparedness of healthcare providers to treat patients, difficulties in obtaining or changes in the availability of reimbursement for IMRALDI, the effectiveness of sales and marketing efforts and problems with the manufacturing process for IMRALDI; 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, including IMRALDI; the occurrence of adverse safety events; failure to obtain regulatory approvals in other jurisdictions; failure to protect intellectual property and other proprietary rights; product liability claims; and third party collaboration risks. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Biogen’s expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in Biogen’s most recent annual or quarterly report and in other reports Biogen has filed with the Securities and Exchange Commission. These statements are based on Biogen’s current beliefs and expectations and speak only as of the date of this press release. Biogen does not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments, or otherwise.

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References

1 Humira® is a registered trademark of AbbVie Biotechnology Ltd.
2 Biogen data on file – ex-factory sales