Samsung Bioepis and Biogen Announce Pooled Analysis Results of Anti-TNF Biosimilars BENEPALI™ (etanercept), FLIXABI™ (infliximab), and IMRALDI™ (adalimumab) at EULA 2018

June 13, 2018

- Pooled analysis is first of its kind, combining data from three Phase III trials that compared efficacy and safety of anti-tumor necrosis factor (anti-TNF) biosimilars to their reference biologics
- Study – which examined patients with moderate to severe rheumatoid arthritis – may help scientists answer critical questions about anti-TNF treatment among specific patient populations
- The potential role of anti-TNF biosimilars in managing autoimmune rheumatological diseases will be discussed at EULAR 2018

INCHEON, Korea & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 13, 2018-- Samsung Bioepis Co., Ltd. and Biogen (Nasdaq:BIIB) today announced pooled analysis results of three anti-tumor necrosis factor (anti-TNF) biosimilars – BENEPALI™ (SB4, etanercept biosimilar), FLIXABI™ (SB2, infliximab biosimilar), and IMRALDI™ (SB5, adalimumab biosimilar) – which will be presented at the AnnuaEuropean Congress of Rheumatology (EULAR 2018) held June 13–16 in Amsterdam, Netherlands.

“Since BENEPALI and FLIXABI launched more than two years ago, they have played an increasingly important role in widening access to life-enhancing treatment options for patients and healthcare systems across Europe,” said Chul Kim, Head of Clinical Sciences Division, Samsung Bioepis. “We remain committed to advancing our strong pipeline of biosimilar candidates, so that more patients and healthcare systems across the region will be able to benefit from biosimilars.”

Data from three separate Phase III randomized, double-blind studies compared the efficacy and safety of BENEPALI in reference to etanercept (ETN); FLIXABI to infliximab (INF); and IMRALDI to adalimumab (ADL). The data were pooled and analyzed to assess the impact of anti-drug antibodies (ADAbs) on efficacy and tolerability, as well as radiographic progression by disease activity state.

Each clinical study had similar study designs and population demographics, and the same primary endpoint of ACR20 response rate. All patients included in the studies had been diagnosed with moderate to severe rheumatoid arthritis (RA) despite previous methotrexate treatment.

“This analysis presents a unique opportunity to compare the efficacy of three anti-TNFs in slowing the progression of joint erosion in patients with moderate to severe RA, as measured by radiographic progression,” said Ian Henshaw, Global Head of Biogen’s Biosimilar Unit. “We look forward to continuing to collaborate with Samsung Bioepis to provide guidance on treatment algorithms and as we work toward our goal of expanding access to biosimilars for patients who may benefit in Europe and around the world.”

Immunogenicity data from 1,710 patients with RA pooled from the three studies revealed that the incidence of ADAb was comparable between the biosimilars and their reference products – indicating that the biosimilars were equally effective as their biologic counterparts. In addition, efficacy and injection site reactions/infusion related reactions (ISR/IRR) were evaluated in relation to the presence of ADAb. Data suggested that the development of ADAb is associated with reduced clinical efficacy and increased incidence of ISR/IRR in patients with RA.

Radiographic data from 1,263 patients participating in the studies were collected and grouped based on patient’s disease activity state at the time of the primary endpoint assessment (Week 24 or Week 30). Radiographic progression was measured using the modified Total Sharp Score (mTSS) at Week 0 and Week 52 or Week 54. Overall, radiographic progression was minimal and comparable across all treatment groups. In addition, the pooled biosimilar group tended to have a lower mean change in mTSS compared with the pooled reference group, which slows down the progression of this disease.

Since the European Commission granted marketing authorization for BENEPALI and FLIXABI in 2016, the two biosimilars have treated nearly 80,000 patients across 23 countries.[i] In addition, Samsung Bioepis and Biogen expect to launch IMRALDI in Europe in October 2018 and, as a result, are on track to be the first in the industry to bring biosimilars referencing products for all three first-generation anti-TNF therapies to European patients and healthcare systems.

The two abstracts being presented at EULAR 2018 are as follows:

- Abstract #THU0201 – A pooled analysis of three TNF-A inhibitor biosimilar studies in patients with rheumatoid arthritis comparing radiographic progression by disease activity states [Poster session: June 14, 2018 at 11:45]
- Abstract #THU0184 – Impact of immunogenicity on clinical efficacy and administration related reaction in TNF inhibitors: a pooled-analysis from three biosimilar studies in patients with rheumatoid arthritis [Poster tour: June 14, 2018 at 12:10]

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 includes six late-stage candidates that cover the therapeutic areas of immunology, oncology and diabetes. Samsung Bioepis is a joint venture between Samsung BioLogics and Biogen. For more information, please visit: www.samsungbioepis.com.

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, 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.

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 results from the three Phase III studies of BENEPALI, FLIXABI and IMRALDI; the potential benefits, effects, safety and efficacy of BENEPALI, FLIXABI and IMRALDI; and planning and timing for commercial launch of IMRALDI; and the potential of Biogen's commercial business and pipeline programs, including BENEPALI, FLIXABI and IMRALDI. These statements may be identified by such words as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "possible," "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 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; the risks of other unexpected hurdles; 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, problems with the manufacturing process for 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 our 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 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, whether as a result of new information, future developments or otherwise.

[i] Biogen data on file

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