Biogen and Samsung Bioepis to Present Data for Infliximab and Adalimumab Biosimilars at United European Gastroenterology Week

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- *Data highlights real-world evidence confirming the safety and efficacy of anti-TNF biosimilars for patients with inflammatory bowel disease (IBD)*

CAMBRIDGE, Mass. and INCHEON, Korea, Oct. 21, 2019 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) and Samsung Bioepis today announced that they will present new real-world data from the companies' anti-TNF biosimilar portfolio, which includes FLIXABI™ (infliximab) and IMRALDI™ (adalimumab). These data, which provide further insight into the long-term safety and efficacy as well as patient experience with anti-TNF biosimilars, are being presented at United European Gastroenterology (UEG) Week 2019 taking place in Barcelona, Spain (October 19-23).

Biosimilars are products that are demonstrated to be highly similar to reference biological product and have the potential to lower drug costs. In Europe, approximately 170,000 patients have been treated with Biogen and Samsung Bioepis' anti-TNF biosimilars. Biogen expects the uptake of these products to generate 1.8 billion euros in healthcare cost savings in 2019.[1]

"Patients living with severe autoimmune diseases such as IBD are looking for long-term treatments to safely and effectively control symptoms and improve their quality of life. Biosimilars now open the door for more patients to access biologic medicines and effectively manage their GI diseases," said Alessandro Armuzzi, M.D., Ph.D., Head, Inflammatory Bowel Disease Unit Complesso Integrato Columbus Catholic University of Rome/Italy.

Four Biogen and Samsung Bioepis supported abstracts will be presented at UEG Week 2019.[2]

Data to be presented at UEG Week 2019 include a clinical evaluation of the switch from reference adalimumab to IMRALDI in 87 patients with IBD – either Crohn's disease or ulcerative colitis. The study results showed an overall similar performance for the serum levels of adalimumab between IMRALDI and reference adalimumab. Moreover, symptom activity indexes and inflammatory markers remained consistent after switching to IMRALDI.[3] [**P1806** – October 23 (Wed), 2019, 09:00-14:00 CET, Poster Exhibition Hall 7]

"We plan to continue to conduct research with the goal of generating data that will enable us to deliver value to patients with high unmet needs," said Ian Henshaw, Vice President and Head of Biogen's Global Biosimilars Unit.

An interim analysis of the non-interventional PERFUSE study will also be presented. This study investigated persistence (the number of patients continuing on treatment) and immunogenicity of FLIXABI in three subsets of IBD patients receiving FLIXABI. These interim results demonstrate high persistence on FLIXABI with no clinical differences observed (disease scores HBA or Simple Clinical Colitis Activity Index (SCCAI)) for the patients who transitioned.[4] [**P1095** – October 22 (Tue), 2019, 09:00-17:00 CET, Poster Exhibition Hall 7]

"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," said Seongwon Han, M.D., Vice President and Lead of Medical Team, Samsung Bioepis.

In addition, early results from the IBISS study are reported. In this real-world cohort of IBD patients transitioning from one infliximab biosimilar (CT-P13) to another (FLIXABI), showed similar effectiveness and safety.[5] [**P0419** - October 21 (Mon), 2019, 10:30-17:00 CET, Poster Exhibition Hall 7]

The fourth abstract to be presented focuses on the personalization and optimization of therapeutic options. [**P0385** - October 21 (Mon), 2019, 10:30-17:00 CET, Poster Exhibition Hall 7]

About FLIXABI ™ (infliximab)
FLIXABI ™ (infliximab), a biosimilar referencing Remicade®[6], was approved by the European Commission (EC) in May 2016 for the treatment of adults with rheumatoid arthritis, 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 when they have not responded to or cannot take other medicines or treatments. FLIXABI is currently available in 17 countries in Europe.[7]

About IMRALDI ™ (adalimumab)
IMRALDI ™ (adalimumab), a biosimilar referencing Humira®[8], was approved by the European Commission (EC) in August 2017 for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, axial spondylarthritis, psoriatic arthritis, psoriasis, pediatric plaque psoriasis, adult and adolescent hidradenitis suppurativa, Crohn's disease, pediatric Crohn's disease, ulcerative colitis and uveitis, pediatric uveitis. IMRALDI is currently available in 19 countries in Europe and is the leading adalimumab biosimilar in six European countries, such as Germany, Spain, Sweden, Poland, Denmark and Czech Republic.[9,10] There are currently over 50,000 patients in Europe receiving treatment with IMRALDI.[1]

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 as well as related therapeutic adjacencies. 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. Today Biogen has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, commercializes biosimilars of advanced biologics and is focused on advancing research programs in multiple sclerosis and neuroimmunology, neuromuscular disorders, movement disorders, Alzheimer's disease and dementia, ophthalmology, immunology, neurocognitive disorders, acute neurology and pain.

We routinely post information that may be important to investors on our website at www.biogen.com. Follow us on social media – Twitter, LinkedIn, Facebook, YouTube.

Biogen Safe Harbor
This news release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, relating to the results of certain real-world data; the potential benefits, safety and efficacy of FLIXABI and IMRALDI; potential clinical effects of FLIXABI and IMRALDI; risks and uncertainties associated with drug development and commercialization; clinical trial results and plans; the potential of Biogen's commercial business, including FLIXABI and IMRALDI; Biogen's strategy and plans; and potential cost healthcare savings related to biosimilars. These statements may be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "potential," "possible," "will," "would" 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 without limitation the occurrence of adverse safety events and/or unexpected concerns that may arise from additional information or further studies; risks of unexpected costs or delays; regulatory authorities may require additional data or information or further studies; risks related to Biogen's dependence on third parties for the development and commercialization of biosimilars; unexpected concerns may arise from additional data, analysis or results obtained during clinical trials; risks of legal actions, regulatory scrutiny or other challenges to biosimilars; the risks of other unexpected hurdles; failure to protect and enforce Biogen's data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; 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 U.S. Securities and Exchange Commission. These statements are based on Biogen's current beliefs and expectations and speak only as of the date of this news release. Biogen does not undertake any obligation to publicly update any forward-looking statements, whether as result of new information, future developments or otherwise.

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, hematology and ophthalmology. Samsung Bioepis is a joint venture between Samsung BioLogics and Biogen.

For more information, please visit: www.samsungbioepis.com and follow us on social media – Twitter, LinkedIn.

References:

1. Biogen data on file.
2. Data from Biogen- and Samsung Bioepis- supported studies.
3. Lukas et al. Impact of the Switch from Original Adalimumab to Biosimilar Adalimumab SB5 on Serum Drug Trough Levels and Clinical and Biological Disease Activity in Patients with IBD. UEG Week 2019.
4. Bouhnik et al. PERFUSE: a French Prospective/Retrospective Non-Interventional Cohort Study of Infliximab Naïve and Transitioned Patients Receiving Infliximab Biosimilar SB2; 1st Interim Analysis. UEG Week 2019.
5. Harris et al. IBD Biosimilar to Biosimilar Infliximab Switching Study: Preliminary Results. UEG Week 2019.
6. Remicade® is a registered trademark of Janssen Biotech, Inc.
7. Data on File: IQVIA, GERS, Insight Health ODV
8. Humira® is a registered trademark of AbbVie Biotechnology Ltd.
9. Data on File: IQVIA, (Aug 2019) GERS, Insight Health ODV

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