IMRALDI™, Biogen's Adalimumab Biosimilar Referencing Humira®, Is Launched in the European Union

October 17, 2018

- *IMRALDI™ is approved in the European Union for the same 14 complex autoimmune conditions as its reference product*
- *In 2017 Biogen became the first company in Europe with approved biosimilars referencing the three most prescribed anti-TNF biologic treatments*

BAAR, Switzerland, Oct. 17, 2018 (GLOBE NEWSWIRE) -- Samsung Bioepis Co. Ltd, a joint venture between Samsung BioLogics and Biogen (Nasdaq: BIIB) today announced the European launch of IMRALDI™, an adalimumab biosimilar referencing Humira®.[1]

IMRALDI is approved in Europe for the treatment of rheumatoid arthritis (RA), juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, paediatric plaque psoriasis, adult and adolescent hidradenitis suppurativa, Crohn's disease, paediatric Crohn's disease, ulcerative colitis and uveitis.

The launch of IMRALDI completes Biogen's portfolio of three anti-TNF biosimilars in Europe, with BENEPALI ™ (etanercept), a biosimilar referencing Enbrel®[2], and FLIXABI™ (infliximab), a biosimilar referencing Remicade®[3], reinforcing the company's commitment across therapeutic areas in rheumatology, gastroenterology and dermatology.

"We are proud to be pioneering innovation in biosimilars to help transform the lives of people in Europe with chronic autoimmune conditions," said Ian Henshaw, Global Head of Biosimilars at Biogen. "With the addition of IMRALDI to our anti-TNF biosimilar offering, we are increasing physician choice and patient access in Europe to affordable treatments across disease areas."

Anti-TNF therapies represent some of the EU's largest drug expenditures, costing an estimated €7.69 billion each year from 2011 to 2014. [4,5] €10.6 billion could potentially be saved by 2020 through the availability of Biogen's three anti-TNF biosimilars in Europe. [6]

IMRALDI has demonstrated equivalent pharmacokinetics (PK) and efficacy together with comparable safety and immunogenicity with the reference product whilst offering a greater shelf life of three years. With IMRALDI, Biogen has stayed as close as possible to the classic 40mg/0.8 ml Humira formulation that has been in use for over a decade, whilst making several improvements to optimize the patient experience, including an innovative device.

Biogen has nearly 40 years of experience of developing, manufacturing and commercializing advanced biologic medicines[7] and has a proven supply chain record, reliably supplying approximately 100,000 patients currently under treatment.[8] Biogen now has an EU-approved portfolio that includes two of the most widely prescribed anti-TNF biosimilars, with BENEPALI available in 25 countries and FLIXABI available in 14 countries.

About IMRALDI Clinical Trials
The European Commission approval was based on a 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[9] and a 52 week Phase III, randomized, double-blind, multicentre study, in which IMRALDI demonstrated comparable efficacy and comparable safety and immunogenicity to Humira in patients with moderate to severe RA despite methotrexate therapy.[10,[11]] 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).[9] 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.

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 I and Phase III studies of

IMRALDI; the potential of Biogen's commercial business, including IMRALDI, BENEPALI and FLIXABI; and risks and uncertainties associated with drug development and commercialization, including the commercialization of IMRALDI. 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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[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 October 2018

[5] Currency exchange rates (rounded). Available at: www.xe.com. Accessed October 2018.

[6] Psachoulia E, et al. 2017 Value Health;20(5):A143

[7] Biogen website. www.Biogen.com. Last accessed 8th October 2018

[8] Delivering on the Potential of Biosimilar Medicines. Report by the IMS Institute of Healthcare Informatics. March 2016

[9] 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.

[10] 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).

[11] 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.