Biogen to Present New Safety and Efficacy Data on Biosimilars and Estimates 1.8 Billion Euros in Savings for the European Healthcare System in 2019

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- *Data to be presented at the European Congress of Rheumatology (EULAR) 2019 highlight real-world evidence confirming the safety and efficacy of anti-TNF biosimilars and high adherence of patients to treatment*
- *Biogen's three biosimilar treatments – BENEPALI™ (etanercept), FLIXABI™ (infliximab) and IMRALDI™ (adalimumab) are estimated to save the European healthcare system 1.8 billion euros in 2019*
- *Biogen and its collaboration partner Samsung Bioepis are the first companies in Europe to market biosimilars that reference the three most prescribed anti-TNF biologic treatments, with approximately 145,000 patients currently on treatment*[1]

CAMBRIDGE, Mass., June 11, 2019 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced that it will present new data at the European Congress of Rheumatology (EULAR) 2019 in Madrid, Spain (June 12-15). The abstracts include real-world data from the company's biosimilar anti-TNF portfolio, which includes BENEPALI ™ (etanercept), FLIXABI ™ (infliximab) and IMRALDI ™ (adalimumab). Biosimilars are products that are demonstrated to be similar to or interchangeable with approved biological product and have the potential to lower drug costs. In Europe, approximately 145,000 patients have been treated with a Biogen biosimilar and the company expects the uptake of these products to generate 1.8 billion euros in healthcare cost savings in 2019.

"These new real-world data reinforce Biogen's ongoing commitment to providing innovative and value-based therapeutic options to tens of thousands of patients with unmet medical need," said Ian Henshaw, vice president and head of Biogen's global biosimilars unit. "The cost savings we generate through our biosimilars business unit will help alleviate global healthcare system burden, which could enable governments to allow broader access to critical therapies."

To compile real-world evidence, physicians ask patients open-ended questions about treatment experience. The real-world data to be presented at EULAR this year provide further insight into patient experience with anti-TNF biosimilars, including adherence data.

"Patients with chronic inflammatory diseases face the reality of a lifetime of ongoing disease management and now biosimilars enable more patients access to those life-changing medicines while providing our healthcare systems significant savings," said Dr. Peter Taylor, Norman Collisson professor of musculoskeletal sciences, Nuffield department of orthopedics, rheumatology and musculoskeletal sciences at the University of Oxford, England. "The new real-world data to be presented at EULAR further establish the comparable safety and efficacy of biosimilars against their reference products."

Biosimilars represent an important component of Biogen's European portfolio. Biosimilar products benefit patients and are strategically important as Biogen works with payers and health systems globally with the goal of creating room in healthcare budgets to provide access for patients to innovative therapies.

Biogen and its collaboration partner Samsung Bioepis will present a total of nine abstracts at the congress. In February 2012 Biogen entered into a joint venture agreement with Samsung BioLogics, establishing an entity, Samsung Bioepis, to develop, manufacture and market biosimilar products.

Data to be presented include results of the real-world data generating BENEFIT study, which evaluated the outcomes of transition from the reference product etanercept to its biosimilar in routine clinical practice. The study demonstrated no clinically significant difference in disease score from baseline to six months post transition in 533 patients suffering from rheumatoid arthritis (RA) and axial spondyloarthritis (axSpA)[2] *(June 14, 11:45.-13:30 CET – FRI0103 – Hall 10).*

Additionally, data from a pooled analysis of etanercept, infliximab and adalimumab biosimilars and reference products across 1,461 patients will be presented. The analysis demonstrated similar outcomes between biosimilars and their respective reference products in terms of disease fluctuation at six months and one year of treatment[3] *(June 15, 10:30-12:00 CET – SAT0162 – Hall 10).*

Further abstracts evaluating the efficacy, safety and retention rates of anti-TNF biosimilars in rheumatology include[4]:

- **[OPO236]** Glintborg et al. ARTIS: Similar one-year treatment retention of originator and biosimilar etanercept. Results of a Nordic collaboration including 1,015 patients with spondyloarthritis *(June 14, 10:15-11:45 CET – Hall 7A).*
- **[SAT0134]** Baganz et al. RABBIT: Comparing real-world retention rates in a matched cohort of rheumatoid arthritis patients who either remained on the etanercept originator or switched to a biosimilar *(June 15, 10:30-12:00 CET – Hall 10).*
- **[SAT0146]** Haugeberg et al. Drug survival for biosimilar SB4 etanercept in rheumatoid arthritis both etanercept naïve and non-medical switch patients with etanercept reference drug in a Norwegian out-patient clinic. Preliminary results from a multi-center study *(June 15, 10:30-12:00 CET – Hall 10).*
- **[FRI0094]** Haugeberg et al. Long-term drug survival for biosimilar SB4 etanercept in RA, PsA and aSpA patients with a non-medical switch from etanercept reference drug *(June 14, 11:45-13:30 CET – Hall 10).*
- **FRI0101]** Kiltz et al. Non-medical switching from originator to biosimilar etanercept - no evidence for a relevant nocebo effect – a retrospective analysis of real-life data. *(June 14, 11:45-13:30 CET – Hall 10).*
- **[SAT0141]** Rebecca Davies et al. BSRBR: Frequency and reasons for switching back to biologic originator following initial switch to biologic biosimilar *(June 15, 10:30-12:00 CET– Hall 10).*

- **[ABSTRACT ONLY]** Ruiz-Argüello et al. Validation of a therapeutic drug monitoring test to measure the adalimumab biosimilar SB5 in comparison to the reference adalimumab (ENCORE).

About BENEPALI ™ (etanercept)
BENEPALI ™ (etanercept), a biosimilar referencing Enbrel®[5], was approved by the European Commission (EC) in January 2016 for the treatment of adults with moderate to severe rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis (ankylosing spondylitis and non-radiographic axial spondyloarthritis) and plaque psoriasis. BENEPALI ™ is currently available in 25 countries in Europe and is the most prescribed etanercept in the five largest European countries (Germany, UK, France, Italy and Spain).[6]

About FLIXABI ™ (infliximab)
FLIXABI ™ (infliximab), a biosimilar referencing Remicade®[7], 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.[8]

About IMRALDI ™ (adalimumab)
IMRALDI ™ (adalimumab), a biosimilar referencing Humira®[9], was approved by the European Commission (EC) in August 2017 for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, axial spondyloarthritis, psoriatic arthritis, psoriasis, pediatric plaque psoriasis, adult and adolescent hidradenitis suppurativa, Crohn's disease, pediatric Crohn's disease, ulcerative colitis and uveitis. IMRALDI is currently available in 18 countries in Europe and is the leading adalimumab biosimilar in Germany and in Europe.[10,11]

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, and today has the leading portfolio of medicines to treat multiple sclerosis (MS), has introduced the first approved treatment for spinal muscular atrophy and is focused on advancing neuroscience research programs in MS and neuroimmunology, Alzheimer's disease and dementia, movement disorders, neuromuscular disorders, acute neurology, neurocognitive disorders, pain and ophthalmology. Biogen also 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 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 BENEPALI, FLIXABI and IMRALDI; risks and uncertainties associated with drug development and commercialization; the potential of Biogen's commercial business and pipeline programs, including BENEPALI, FLIXABI and IMRALDI; anticipated benefits and potential of investments, collaborations and business development activities; Biogen's strategy and plans; potential cost healthcare savings related to biosimilars. These statements may be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "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, or may fail to approve, or refuse to approve, or may delay approval of Biogen's biosimilar drug candidates; 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.

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References:
1. Biogen data on file.
2. Kruger et al. BENEFIT Study: A Pan-European Observational Study to Evaluate Real-world Effectiveness of SB4 Following Transition from

Originator Etanercept (ETN) in Patients with Rheumatoid Arthritis (RA) or Axial Spondyloarthritis (AxSpA). EULAR 2019.
3. Smolen et al. A pooled analysis of 1-year clinical outcome by 6-month disease activity from three TNF inhibitor biosimilar studies in patients with rheumatoid arthritis. EULAR 2019.
4. Data from Biogen- and Samsung Bioepis- supported studies.
5. Enbrel® is a registered trademark of Wyeth LLC.
6. Data on File: IQVIA, GERS, Insight Health ODV
7. Remicade® is a registered trademark of Janssen Biotech, Inc.
8. Data on File: IQVIA, GERS, Insight Health ODV
9. Humira® is a registered trademark of AbbVie Biotechnology Ltd.
10. Data on File: IQVIA, GERS, Insight Health ODV
11. Data on File: Biogen, Inc. Q1 First Quarter 2019 Financial Results and Business Update. April 24th, 2019.