Biogen to Expand Biosimilars Portfolio and Gain Access to Additional Markets Through New Transaction with Samsung Bioepis

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- Biogen to gain exclusive commercialization rights to two new ophthalmology biosimilars referencing Lucentis and Eylea in the U.S., Canada, Europe, Japan and Australia
- Will provide Biogen with commercialization rights for its current anti-TNF biosimilars portfolio in China, adding to its strategic presence in this priority market
- Includes an option to extend the term of its existing European commercial agreement

CAMBRIDGE, Mass., Nov. 06, 2019 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced a new proposed transaction with Samsung Bioepis Co., Ltd. to secure the exclusive rights to commercialize two new ophthalmology biosimilars, SB11 referencing Lucentis®[1] and SB15 referencing Eylea®[2], in major markets worldwide, including the U.S., Canada, Europe, Japan and Australia. In addition, Biogen will acquire exclusive commercialization rights for its anti-TNF portfolio, including BENEPALI™ (etanercept), FLIXABI™ (infliximab) and IMRALDI™ (adalimumab), in China. Biogen will also acquire an option to extend its existing commercial agreement with Samsung Bioepis for this anti-TNF portfolio in Europe.

"We are excited about the potential to bring biosimilars to a new therapeutic area as well as new regions around the world with the goal of sustainably advancing broad access to care for patients in need," said Michel Vounatsos, Biogen's Chief Executive Officer. "This transaction would expand the potential for our leading biosimilars business worldwide, while complementing Biogen's presence in ophthalmology."

Biosimilars are products that have been demonstrated to be similar in efficacy and safety to the originator's approved biological product, with the advantage that they offer cost savings and promote sustainable access to therapies. In Europe, over 180,000 patients have been treated with a Biogen anti-TNF biosimilar, and, based on its internal estimates, the company expects the uptake of BENEPALI, FLIXABI and IMRALDI to generate approximately 1.8 billion Euros in healthcare cost savings in 2019[3].

The proposed addition of the two ophthalmology biosimilars complements Biogen's expanding efforts in this therapeutic area. Through the recent acquisition of Nightstar Therapeutics plc, a clinical-stage gene therapy company focused on treatments for inherited retinal disorders, Biogen acquired two mid- to late-stage clinical assets, as well as several preclinical programs, in ophthalmology.

Lucentis and Eylea are therapies widely used to treat ophthalmologic conditions such as neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), diabetic macular edema (DME) and diabetic retinopathy (DR) in patients with DME. In 2018 global sales for Lucentis and Eylea were almost $11 billion, with more than $5.8 billion spent in the U.S. alone[4].

Chirfi Guindo, Executive Vice President and Head of Global Product Strategy and Commercialization at Biogen, added "We believe savings enabled by biosimilars provide payers and health systems globally the budgetary headroom to fund innovation. According to a 2017 RAND Report, in the U.S. alone savings generated from biosimilar uptake could reach as high as $150 billion over a ten-year period[5]. We look forward to expanding our biosimilars portfolio in major markets worldwide."

Under the terms of the proposed transaction, Biogen will make a $100 million upfront payment to Samsung Bioepis. Additionally, Biogen may pay Samsung Bioepis up to $210 million in additional development, regulatory and sales-based milestones. Samsung Bioepis will be responsible for development and will supply both products to Biogen at a pre-specified gross margin.

Biogen will also obtain an option to extend the term of its current European commercial agreement for its three anti-TNF biosimilars by an additional five years, subject to payment of an option exercise fee of $60 million.

Biogen will also receive exclusive commercialization rights to BENEPALI, FLIXABI and IMRALDI in China in exchange for a royalty on sales in that market.

Upon closing, Biogen expects to record a charge to research and development expense of approximately $65 million related to the $100 million upfront payment.

The proposed transaction is subject to customary closing conditions, including the expiration of the applicable waiting period under the Hart Scott Rodino Antitrust Improvements Act of 1976 in the U.S. Biogen expects the deal to close in the fourth quarter of 2019.

About BENEPALI (etanercept)

BENEPALI (etanercept), a biosimilar referencing Enbrel®[6], 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)[7].

About FLIXABI (infliximab)

FLIXABI (infliximab), a biosimilar referencing Remicade®[8], 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[9].

About IMRALDI (adalimumab)

IMRALDI (adalimumab), a biosimilar referencing Humira®[10], 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 19 countries in Europe and is the leading adalimumab biosimilar in Germany and in Europe[11,12].

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. 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 and follow us on social media – Twitter, LinkedIn.

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 potential benefits and results that may be achieved through Biogen's proposed transaction with Samsung Bioepis; the anticipated completion and timing of the proposed transaction; Biogen's objectives and intentions regarding the option to extend the term of its European commercial agreement with Samsung Bioepis; when, and whether, Biogen expects to exercise its option to extend the term of its European commercial agreement with Samsung Bioepis; the potential benefits, safety and efficacy of SB11 and SB15; the timing and status of current and future regulatory filings; risks and uncertainties associated with drug development and commercialization, including SB11 and SB15; the potential of Biogen's commercial business and pipeline programs, including BENEPALI, FLIXABI, IMRALDI, SB11 and SB15; the anticipated benefits and potential of Biogen's collaboration arrangements with Samsung Bioepis; Biogen's strategy and plans; Biogen's capital allocation and investment strategy; Biogen's future financial and operating results; and potential cost healthcare savings related to biosimilars. These forward-looking statements may be accompanied 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, risks that the proposed transaction will be completed in a timely manner or at all; the possibility that certain closing conditions to the proposed transaction will not be satisfied; uncertainty as to whether the anticipated benefits of the proposed transaction and/or the Samsung Bioepis joint venture can be achieved; risks of unexpected costs or delays; uncertainty of success in the development and potential commercialization of SB11 and SB15, which may be impacted by, among other things, the occurrence of adverse safety events, unexpected concerns that may arise from additional data or analysis, failure to obtain regulatory approvals in certain jurisdictions, failure to protect and enforce data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; risks of legal actions, regulatory scrutiny or other challenges to biosimilars; the risks of other unexpected hurdles; the risks of doing business internationally, including currency exchange rate fluctuations; 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 a result of new information, future developments or otherwise.

[1]Lucentis is a registered trademark of Genentech.

[2]Eylea is a registered trademark of Regeneron Pharmaceuticals, Inc.

[3]Biogen data on file.

[4]Source: company reported sales, EvaluatePharma.

[5]Mulcahy, Andrew W., Jakub P. Hlavka, and Spencer R. Case, Biosimilar Cost Savings in the United States: Initial Experience and Future Potential. Santa Monica, CA: RAND Corporation, 2017

[6]Enbrel is a registered trademark of Wyeth LLC.

[7]Data on file: IQVIA, GERS, Insight Health ODV.

[8]Remicade is a registered trademark of Janssen Biotech, Inc.

[9]Data of file: IQVIA, GERS, Insight Health ODV.

[10]Humira is a registered trademark of AbbVie Biotechnology Ltd.

[11]Data on file: IQVIA, GERS, Insight Health ODV.

[12]Biogen data on file.

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