Samsung Bioepis and Biogen Announce EMA Filing Acceptance of SB11, a Proposed Biosimilar Referencing Lucentis® (ranibizumab)

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INCHEON, South Korea and CAMBRIDGE, Mass., Oct. 06, 2020 (GLOBE NEWSWIRE) -- Samsung Bioepis Co., Ltd. and Biogen Inc. (Nasdaq: BIIB) today announced that the European Medicines Agency (EMA) has accepted for review the Marketing Authorisation Application for SB11, a proposed biosimilar referencing Lucentis® (ranibizumab). Ranibizumab is an anti-VEGF (vascular endothelial growth factor) for retinal vascular disorders, which are a leading cause of blindness. If approved, SB11 will join a growing number of biosimilars developed by Samsung Bioepis and commercialized by Biogen.

“The EMA filing acceptance for SB11 (ranibizumab) further demonstrates the productive collaboration between Samsung Bioepis and Biogen and brings us closer to our shared goal of offering new affordable treatment options for people with retinal vascular disorders,” said Hee Kyung Kim, Senior Vice President, Clinical Sciences and Regulatory Affairs Division Lead at Samsung Bioepis. “We believe SB11 has the potential to be a meaningful new offering for patients with retinal vascular disorders, and we look forward to continued engagement with the EMA throughout the review process.”

“The EMA acceptance of the SB11 (ranibizumab) application is an important step as we work to bring a new potential treatment option for patients with retinal vascular disorders and would represent a significant addition to our biosimilar portfolio,” said Ian Henshaw, Senior Vice President and Global Head of Biosimilars at Biogen. “We believe our biosimilar offerings are essential as we collaborate with payers and health authorities globally with the goal of creating budget headroom to fund innovation and ensure sustainable healthcare systems.”

Samsung Bioepis announced in November 2019 that it entered into a new commercialization agreement with Biogen for two ophthalmology biosimilar candidates, SB11 (ranibizumab) and SB15 (aflibercept), in the United States (U.S.), Canada, Europe, Japan and Australia.

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, ophthalmology and hematology. 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.

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, 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, Alzheimer’s disease and dementia, neuromuscular disorders, movement disorders, 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 http://www.biogen.com and follow us on social media – Twitter, LinkedIn, Facebook, YouTube.

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, safety and efficacy of SB11; 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 SB11 and SB15; the anticipated benefits and potential of Biogen’s collaboration arrangements with Samsung Bioepis; Biogen’s strategy and plans; 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, actual timing and content of submissions to and decisions made by the regulatory authorities regarding SB11; regulatory submissions may take longer or be more difficult to complete than expected; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of SB11; risks of unexpected costs or delays or other unexpected hurdles; uncertainty of success in the development and potential commercialization of SB11, 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 SB11 and other unexpected difficulties or hurdles; the occurrence of adverse safety events; unexpected concerns that may arise from additional data or analysis; 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 direct and indirect impacts of the ongoing COVID-19 pandemic on Biogen’s business, results of operations and financial condition; 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.

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