Samsung Bioepis and Biogen Receive Positive CHMP Opinion for Ranibizumab Biosimilar, BYOOVIZ™

June 25, 2021

INCHEON, Korea and CAMBRIDGE, Mass., June 25, 2021 (GLOBE NEWSWIRE) -- Samsung Bioepis Co., Ltd. and Biogen Inc. (Nasdaq: BIIB) today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for BYOOVIZ™, a biosimilar candidate referencing Lucentis® (ranibizumab), also known as SB11. Ranibizumab is an anti-VEGF (vascular endothelial growth factor) for retinal vascular disorders, which are a leading cause of blindness. BYOOVIZ has been recommended for approval for the treatment of neovascular (wet) age-related macular degeneration (AMD), visual impairment due to diabetic macular oedema (DME), proliferative diabetic retinopathy (PDR), visual impairment due to macular odemea secondary to retinal vein occlusion (branch RVO or central RVO) and visual impairment due to choroidal neovascularization (CNV) in the European Union (EU).

The CHMP's positive opinion will now be referred to the European Commission (EC), which will decide whether to grant a marketing authorization for BYOOVIZ. If a marketing authorization is granted by the EC, BYOOVIZ would be added to the biosimilars portfolio developed by Samsung Bioepis and commercialized by Biogen, including three widely prescribed anti-TNF biosimilars in Europe: BENEPALI™, IMRALDI™ and FLIXABI™

"We are very proud to see BYOOVIZ becoming the first biosimilar of ranibizumab to be recommended for approval in Europe. This marks an important milestone for our company, as this is one step forward to expanding patient access to treatments for retinal vascular disorders," said Kyung-Ah Kim, Senior Vice President and Development Division at Samsung Bioepis. "We will continue our efforts to develop and deliver high-quality and proven biologic medicines to more patients and healthcare systems in Europe."

"Retinal vascular disorders affect millions of people, and we believe BYOOVIZ has the potential to be a meaningful therapeutic offering for patients living with these disorders," said Ian Henshaw, Global Head of Biosimilars at Biogen. "Biosimilars could help broaden access and offer significant healthcare savings through the treatment of these complex and often debilitating ophthalmic diseases."

This positive CHMP opinion on BYOOVIZ was based on a Phase 3 clinical study that demonstrated equivalence in efficacy for both primary endpoints. The adjusted treatment differences between groups were within predefined equivalence margins for mean changes from baseline in both best corrected visual acuity (BCVA) and in central subfield thickness (CST). The improvements in the primary efficacy outcomes remained stable and appeared comparable between treatment groups at all time points up to week 52.

In November 2019, Samsung Bioepis and Biogen announced that they had entered into a commercialization agreement for two ophthalmology biosimilar candidates, BYOOVIZ (SB11, ranibizumab) and SB15 (aflibercept), in the U.S., Canada, Europe, Japan and Australia.

Additionally, the Biologics License Application for SB11 was accepted for review by the U.S. Food and Drug Administration in November 2020.

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, hematology and endocrinology. 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. 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, Alzheimer's disease and dementia, neuromuscular disorders, movement disorders, ophthalmology, neuropsychiatry, immunology, acute neurology and neuropathic 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.

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; the potential of Biogen's commercial business and pipeline programs, including BENEPALI, IMRALDI, FLIXABI and SB11; 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; 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.

References:

[1]Lucentis is a registered trademark of Genentech, Inc.

Media Contact - Samsung Bioepis

[EU news release] Yoon Kim: +82-31-8061-1783, yoon1.kim@samsung.com

[US news release] Anna Nayun Kim: 82+31-8061-1604, nayun86.kim@samsung.com

Media Contact - Biogen

For Investors: Mike Hencke, +1 781 464-2442, IR@biogen.com

For Media: Allison Parks, +1 781 464-3260, public.affairs@biogen.com