Biogen and Samsung Bioepis' BYOOVIZ™ (ranibizumab-nuna) Launches in the United States

June 2, 2022

- BYOOVIZ™ is the first FDA approved ophthalmology biosimilar
- BYOOVIZ, priced 40% lower than LUCENTIS®, provides an equally effective and more affordable treatment option to patients suffering from retinal disorders
- BYOOVIZ will be commercially available through major distributors across the U.S. on July 1, 2022

CAMBRIDGE, Mass. and INCHEON, Korea – June 02, 2022 – Biogen Inc. (Nasdaq: BIIB) and Samsung Bioepis Co., Ltd. today announced that BYOOVIZ™ (ranibizumab-nuna), a biosimilar referencing LUCENTIS® (ranibizumab)[i] has been launched in the United States. Healthcare provider engagement, promotional activity, collaborations with professional societies and patient advocacy groups have commenced and BYOOVIZ will be commercially available on July 1, 2022, through major distributors across the U.S. The list price will be $1,130 per single use vial to administer 0.5mg via intravitreal injection, which is 40% lower than the current list price of LUCENTIS.

The FDA approved BYOOVIZ in September 2021 for the treatment of neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion, and myopic choroidal neovascularization.

Neovascular (wet) AMD, although less common than dry AMD, is responsible for the majority of the severe vision loss or blindness associated with AMD.[ii] Anti-VEGF therapies have become a standard of care treatment for wet AMD, but in real-world settings, costs related with wet AMD treatment often raise challenges in achieving optimal clinical outcomes.[iii] Biosimilars, which are biologics with similar efficacy and comparable safety to reference biologics,[iv] have the potential to alleviate the financial burden associated with current anti-VEGF therapies.

"The launch of BYOOVIZ in the U.S. marks an important moment for patients, healthcare providers, payers, and the entire healthcare system. Patients suffering from retinal vascular disorders now have a more affordable treatment option," said Ian Henshaw, Senior Vice President and Global Head of Biosimilars at Biogen. "Our research with physicians shows cost is cited as a leading barrier to patients initiating treatment, with one third of patients unable to afford medication. BYOOVIZ has the potential to expand access to patients suffering from retinal disorders that can result in permanent vision loss, while also saving the U.S. healthcare system billions of dollars."

"The launch of BYOOVIZ, the first ophthalmology biosimilar in the U.S. marks a key step towards increasing options and reducing the financial burden associated with current anti-VEGF treatments," said Christopher Hansung Ko, President and Chief Executive Officer, at Samsung Bioepis. "The priority of Samsung Bioepis is ensuring patients' access to the medicines they need, and we will continue to advance our pipeline to bring better access to biologic treatments, by leveraging our decade of experience in developing, manufacturing, and commercializing these important biologics." he added.

BYOOVIZ is the first biosimilar launch in the U.S. under the Biogen and Samsung Bioepis' partnership. In addition to the U.S., BYOOVIZ was also approved as the first ophthalmology biosimilar in Europe (2021), the United Kingdom (2021), and Canada (2022). The Biogen and Samsung Bioepis commercialization agreement includes two ophthalmology biosimilar candidates, BYOOVIZ and SB15, a biosimilar candidate referencing EYLEA® (aflibercept)[v]. Samsung Bioepis is responsible for development, regulatory registration, and manufacture of the products, while Biogen is responsible for commercialization.

About BYOOVIZ™ (ranibizumab-nuna)

BYOOVIZ™ (ranibizumab-nuna) injection, for intravitreal use.

BYOOVIZ™ (ranibizumab-nuna) is biosimilar to LUCENTIS® (ranibizumab injection).

BYOOVIZ™, a vascular endothelial growth factor (VEGF) inhibitor, is indicated for the treatment of patients with:

Neovascular (Wet) Age-Related Macular Degeneration (AMD)

Macular Edema Following Retinal Vein Occlusion (RVO)

Myopic Choroidal Neovascularization (mCNV)

Select Important Safety Information

WARNING AND PRECAUTIONS

Endophthalmitis and retinal detachments may occur following intravitreal injections. Patients should be monitored following the injection.

Increases in intraocular pressure (IOP) have been noted both pre- and post-intravitreal injection.

There is a potential risk of arterial thromboembolic events following intravitreal use of VEGF inhibitors.

Please see Prescribing Information for BYOOVIZ™ (ranibizumab-nuna) HERE.

About Biogen

As pioneers in neuroscience, Biogen discovers, develops, and delivers worldwide innovative therapies for people living with serious neurological 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, Sir Kenneth Murray, and Nobel Prize winners Walter Gilbert and Phillip Sharp. Today, Biogen has a leading portfolio of

medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, and developed the first and only approved treatment to address a defining pathology of Alzheimer's disease. Biogen is also commercializing biosimilars and focusing on advancing one of the industry's most diversified pipeline in neuroscience that will transform the standard of care for patients in several areas of high unmet need.

In 2020, Biogen launched a bold 20-year, $250 million initiative to address the deeply interrelated issues of climate, health, and equity. Healthy Climate, Healthy Lives™ aims to eliminate fossil fuels across the company's operations, build collaborations with renowned institutions to advance the science to improve human health outcomes, and support underserved communities.

The company routinely posts information that may be important to investors on its website at www.biogen.com. To learn more, please visit www.biogen.com and follow Biogen 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 potential benefits, safety and efficacy of BYOOVIZ™; the timing and status of current and future regulatory filings; risks and uncertainties associated with drug development and commercialization, including BYOOVIZ™; 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, uncertainty of success in the commercialization of BYOOVIZ™, 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 BYOOVIZ™ 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.

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, endocrinology, and gastroenterology. For more information, please visit: www.samsungbioepis.com and follow us on social media – Twitter, LinkedIn.

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[i] LUCENTIS® is a registered trademark of Genentech

[ii] American Academy of Ophthalmology. Age-Related Macular Degeneration Preferred Practice Pattern®. Available at: https://www.aaojournal.org/article/S0161-6420(19)32091-3/fulltext. Accessed June 2022.

[iii] Wykoff et al. Optimizing Anti-VEGF Treatment Outcomes for Patients with Neovascular Age-Related Macular Degeneration. J Manag Care Spec Pharm, 2018 Feb;24(2-a Suppl):S3-S15. https://doi.org/10.18553/jmcp.2018.24.2-a.s3

[iv] U.S. Food and Drug Administration. Biosimilar and Interchangeable Products. Available at: https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products. Accessed June 2022.

[v] EYLEA® is a registered trademark of Regeneron Pharmaceuticals