FDA Approves Samsung Bioepis and Biogen's BYOOVIZ™ (SB11), LUCENTIS® Biosimilar (ranibizumab-nuna)

September 20, 2021

- **BYOOVIZ™ becomes the first ophthalmology biosimilar to gain FDA approval in the United States**

INCHEON, Korea and CAMBRIDGE, Mass., Sept. 20, 2021 (GLOBE NEWSWIRE) -- Samsung Bioepis Co., Ltd. and Biogen Inc. (Nasdaq: BIIB) today announced that the U.S. Food and Drug Administration (FDA) has approved BYOOVIZ™ (ranibizumab-nuna), a biosimilar referencing LUCENTIS® (ranibizumab)[i] for the treatment of neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), and myopic choroidal neovascularization (mCNV).

Ranibizumab is an anti-vascular endothelial growth factor (VEGF) therapy that prevents vision loss in patients with retinal vascular disorders which can cause irreversible blindness or visual impairments in adults in the United States (U.S.). [ii,iii,iv,v]

BYOOVIZ™ is the first ophthalmology biosimilar approved in the United States. Biosimilars are products that have been demonstrated to be similar in efficacy and safety to the originator's reference product, with the advantage that they offer cost savings and promote sustainable access to therapies. [vi] Savings in the United States over the next five years from 2020 to 2024 as a result of biosimilars are projected to exceed $100 billion. [vii]

"In the United States, approximately 11 million people are affected with AMD and the prevalence of advanced AMD is growing due to the aging population. The approval of the first ranibizumab biosimilar in the U.S. is a monumental milestone for people living with retinal vascular disorders in the U.S.," said Kyung-Ah Kim, Senior Vice President and Development Division Leader, at Samsung Bioepis. "The approval of BYOOVIZ™ underscores our continued commitment to providing valuable treatment options for people who do not have access to life-enhancing biologic medicines around the world," she added.

"We are very excited to be able to open a new chapter with the approval of BYOOVIZ™ in the U.S. This approval represents a great step toward the advancement of a new therapeutic option addressing debilitating disease progression of patients with retinal vascular disorders in the U.S.," said Ian Henshaw, Senior Vice President and Global Head of Biosimilars at Biogen. "Biosimilars could help broaden patient access to more affordable treatments and generate healthcare savings to offset rising costs of these complex diseases while ensuring sustainability of healthcare systems."

In addition to the U.S. approval, BYOOVIZ™ was approved in Europe, including 27 European Union (EU) member countries on August 18, 2021 and the United Kingdom on August 31, 2021.

Samsung Bioepis and Biogen entered into a commercialization agreement for two ophthalmology biosimilar candidates, SB11, a biosimilar candidate referencing LUCENTIS® (ranibizumab) and SB15, a biosimilar candidate referencing EYLEA® (aflibercept) [vi], in November 2019. Developed by Samsung Bioepis, SB11 will be commercialized under the brand name BYOOVIZ™ by Biogen in the United States. Pursuant to a global license agreement entered into with Genentech, Samsung Bioepis and Biogen will have freedom to market SB11 in the United States as of June 2022, i.e., before expiration of Genentech's applicable supplementary protection certificates (SPCs), and elsewhere in other territories after expiration of Genentech's SPCs.

The FDA approval of BYOOVIZ™ was based on a totality of evidence including analytical, non-clinical data, and clinical data. In a randomized, double-masked, parallel group, multicenter Phase 3 study of SB11, the efficacy, safety, pharmacokinetics, and immunogenicity of SB11 was compared to reference ranibizumab in patients with wet AMD. 705 patients were randomized (1:1) to receive SB11 or reference ranibizumab in monthly injections (0.5 mg), and 634 patients continued to receive treatment up to week 48. The Least Squares (LS) mean change in best corrected visual acuity (BCVA) from baseline at week 52 was 9.79 letters for SB11, compared with 10.41 letters for reference ranibizumab (difference: -0.62, [90% CI: -2.092, 0.857]). The LS mean change in central subfield thickness (CST) was −139.55 µm for SB11 vs −124.46 µm for reference ranibizumab (difference: -15.09, [95% CI, -25.617, -4.563]). PK, safety including incidence of treatment-emergent adverse events, and the immunogenicity profile of SB11 and reference ranibizumab were comparable at all timepoints up to week 52.

BYOOVIZ™ (ranibizumab-nuna) is Samsung Bioepis' fifth biosimilar approved in the U.S., following the approval of RENFLEXIS® (infliximab-abda) in April 2017, ONTRUZANT® (trastuzumab-dttb) in January 2019, ETICOVO® (etanercept-ykro) in April 2019, and HADLIMA™ (adalimumab-bwwd) in July 2019.

Please see full indications and important safety information for BYOOVIZ™ below.

About BYOOVIZ™ (ranibizumab-nuna)

BYOOVIZ™ is approved in the U.S. for the following indications:

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 neovascular (wet) age-related macular degeneration (AMD)

Age-related macular degeneration (AMD) is the leading cause of irreversible blindness in adults over 50 years old. Approximately 11 million individuals are affected with AMD in the US alone. Wet AMD is responsible for 80 to 90 % of all AMD-related blindness. [iii,vii]

About macular edema following retinal vein occlusion (RVO)

Central retinal vein occlusion (RVO) is a common cause of retinal disease that can cause vision loss. Vision loss from CRVO is commonly caused by macular edema, which occurs when fluid leaks into the macula (center of the retina) as a result of blocked blood vessel.[vii]

About myopic choroidal neovascularization (mCNV)

Myopia is one of the most common causes of vision impairment, and one of the most feared complications of myopia is the development of choroidal neovascularization (CNV). Myopic CNV can occur in patients with any degree of myopia, even in the absence of characteristic degenerative retinal changes. [v]

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.

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.

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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.

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References:

[i] LUCENTIS® is a registered trademark of Genentech

[ii] Spitzer MS, Ziemssen F, Bartz-Schmidt KU, Gelisken F, Szurman P. Treatment of age-related macular degeneration: focus on ranibizumab. *Clin*

Ophthalmol. 2008;2(1):1-14. doi:10.2147/opth.s1959

[iii] "What Is Macular Degeneration?" American Academy of Ophthalmology website. Jan 26, 2021. Available at: https://www.aao.org/eye-health/diseases/amd-macular-degeneration. Accessed July 2021.

[iv] "Untangling Retinal Vein Occlusion" EyeNet Magazine, November 2013. Available at: https://www.aao.org/eyenet/article/untangling-retinal-vein-occlusion. Accessed July 2021.

[v] "Myopic Choroidal Neovascularization." Ophthalmic Pearls, vol. March 2020. Available at: https://www.aao.org/eyenet/article/myopic-choroidal-neovascularization. Accessed July 2021.

[vi] "Biosimilar and Interchangeable Products." U.S. Food and Drug Administration website. Oct 23, 2017. Available at: https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products. Accessed September 2021.

[vii] IQVIA Institute for Human Data Science. Biosimilars in the United States 2020–2024 Competition, Savings, and Sustainability Institute Report, Sep 29, 2020. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2020-2024. Accessed September 2021.

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

[ix] "Blindness Due to Age-Related Macular Degeneration Should Not be Considered an Inevitability" [News Release]. American Academy of Ophthalmology. Feb 06, 2014. Available at: https://www.aao.org/newsroom/news-releases/detail/blindness-due-to-agerelated-macular-degeneration-s. Accessed July 2021.

[x] "What Causes Macular Edema?" American Academy of Ophthalmology website. Oct. 22, 2020. Available at: https://www.aao.org/eye-health/diseases/macular-edema-cause. Accessed July 2021.

(This release was updated on September 20, 2021 to correctly indicate the definition of SPC as supplementary protection certificates.)