Biogen Reaches Agreement with Genentech to Receive Royalties on the Potential Commercialization of a Late-Stage Bispecific Antibody as Part of Anti-CD20 Collaboration

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- Glofitamab is an investigational T-cell engaging bispecific antibody targeting CD20 and CD3 in development for B-cell non-Hodgkin's lymphoma and other blood cancers

CAMBRIDGE, Mass., Dec. 19, 2022 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) announced that it has reached an agreement with Genentech, a member of the Roche Group, related to the commercialization and sharing of economics for glofitamab. Under the terms of the agreement, Biogen will have no payment obligations and will receive tiered royalties on potential net sales of glofitamab within the United States as part of the companies long-standing collaboration on antibodies targeting CD20.

Glofitamab is an investigational CD20xCD3 T-cell engaging bispecific antibody being developed by Roche for the treatment of B-cell non-Hodgkin's lymphomas, including diffuse large B-cell lymphoma (DLBCL), mantle cell lymphoma, and other blood cancers[1]. Glofitamab is based on a novel structural format called '2:1', which is engineered to have two 'Fab' regions that bind to CD20 and one 'Fab' region which binds to CD3. This dual targeting activates and redirects a patient's own T-cells to engage and eliminate cancer B cells.

Data from the Phase II NP30179 study investigating glofitamab in patients with relapsed/refractory (R/R) DLBCL have been submitted for review to the European Medicines Agency (EMA), and submissions to additional health authorities worldwide, including the U.S. Food and Drug Administration, are ongoing. If approved, glofitamab has the potential to be a first-in-class fixed-duration CD20xCD3 T-cell engaging bispecific antibody in DLBCL.

Genentech will have sole decision-making rights on the commercialization of glofitamab within the United States and, in the event of approval, Biogen is eligible to receive tiered royalties in the mid-single digits range on potential net sales of glofitamab within the United States.

Glofitamab, together with mosunetuzumab, is part of the Roche and Genentech CD20xCD3 antibody portfolio that seeks to address the unmet needs of people living with blood cancers. In January 2022, Biogen exercised the option to have joint decision-making rights related to the development and potential commercialization of mosunetuzumab, and Genentech will continue to lead the strategy and implementation of the program. The companies have had a collaboration on antibodies targeting CD20 since 1995.

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 pipelines in neuroscience that will transform the standard of care for patients in several areas of high unmet need.

We routinely post information that may be important to investors on our website at www.biogen.com. Follow us 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, including statements about potential clinical effects of glofitamab; the potential benefits, safety and efficacy of glofitamab; the clinical development program for glofitamab; the identification and treatment of B-cell non-Hodgkin's lymphomas; our collaboration with Genentech; the potential of our commercial business and pipeline programs and risks and uncertainties associated with drug development and commercialization. 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 development and potential commercialization of glofitamab; the risk that we may not fully enroll our clinical trials or enrollment will take longer than expected; unexpected concerns may arise from additional data, analysis or results obtained during our clinical trials; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of our drug candidates, including glofitamab; the occurrence of adverse safety events; the risks of unexpected hurdles, costs or delays; failure to protect and enforce our data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; product liability claims; and the direct and indirect impacts of the ongoing COVID-19 pandemic on our business, results of operations and financial condition. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in our most recent annual or quarterly report and in other reports we have filed with the U.S. Securities and Exchange Commission. These statements are based on our current beliefs and expectations and speak only as of the date of this news release.

We do not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

References:

1. https://www.gene.com/media/press-releases/14954/2022-05-26/new-pivotal-data-demonstrate-clinical-be

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