Biogen Exercises Option to Participate in the Development and Commercialization of a Late-Stage Bispecific Antibody

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- Mosunetuzumab is an investigational T-cell engaging bispecific antibody targeting CD20 and CD3 in development for B-cell non-Hodgkin's lymphoma and other therapeutic areas

CAMBRIDGE, Mass., Feb. 01, 2022 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced that it exercised its option to participate in the development and commercialization of mosunetuzumab. Biogen will pay a $30 million one-time option fee to Genentech, a member of the Roche Group, as part of the companies' long-standing collaboration on antibodies targeting CD20.

Mosunetuzumab is a CD20xCD3 T-cell engaging bispecific antibody in development for the treatment of people with B-cell non-Hodgkin's lymphoma (NHL), including follicular lymphoma (FL)[1] and diffuse large B-cell lymphoma (DLBCL). In June 2020, mosunetuzumab was granted Breakthrough Therapy Designation (BTD) by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with relapsed/refractory (R/R) FL who have received at least two prior systemic therapies.

Genentech plans to complete a Biologics License Application (BLA) submission to the FDA in the near future for approval consideration from the GO29781 study investigating mosunetuzumab in patients with R/R FL. If approved, mosunetuzumab has the potential to be a first-in-class CD20xCD3 T-cell engaging bispecific antibody in NHL. Roche recently submitted the initial marketing authorization application for mosunetuzumab to the European Medicines Agency (EMA), with the hope to bring this drug as soon as possible to people with NHL. In addition, mosunetuzumab recently began a Phase 1b trial in patients with systemic lupus erythematosus[2].

As a part of the option exercise, Biogen will pay a $30 million one-time option fee to Genentech and will pay for a portion of the mosunetuzumab development expenses incurred during 2021. Biogen will have joint decision-making rights related to development and commercialization of mosunetuzumab and Genentech will continue to lead the strategy and implementation of the program.

Biogen will share in the operating profits and losses of mosunetuzumab in United States in the low to mid 30% range and is eligible to receive low single-digit royalties on sales outside the United States.

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 is providing the first and only approved treatment to address a defining pathology of Alzheimer's disease. Biogen is also commercializing biosimilars and focusing on advancing 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, including statements about potential clinical effects of mosunetuzumab; the potential benefits, safety and efficacy of mosunetuzumab; the clinical development program for mosunetuzumab; the identification and treatment of non-Hodgkin's lymphoma or lupus; our research and development program for the treatment of non-Hodgkin's lymphoma or lupus; the potential of our commercial business and pipeline programs, including mosunetuzumab; 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 mosunetuzumab; 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 mosunetuzumab; 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/14938/2021-12-11/genentech-presents-pivotal-data-at-ash-2
2. https://clinicaltrials.gov/ct2/show/NCT05155345

MEDIA CONTACT:
Biogen
Ashleigh Koss
+ 1 908 205 2572
public.affairs@biogen.com

INVESTOR CONTACT:
Biogen
Mike Hencke
+1 781 464 2442
IR@biogen.com