Biogen Presents Positive Results from Phase 2 IGNAZ Study of Felzartamab in IgA Nephropathy at American Society of Nephrology (ASN) Kidney Week 2024

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- The detailed study results confirmed interim findings, showing stable kidney function and sustained treatment effect more than 18 months after the last dose of felzartamab
- Felzartamab, an investigational anti-CD38 monoclonal antibody, is a potential first-in-class therapeutic candidate for a range of rare immune-mediated indications with planning underway for Phase 3 development
- IgA Nephropathy (IgAN) is a leading cause of chronic kidney disease with up to 40% of IgAN patients progressing to end stage kidney disease about 20 years after diagnosis

CAMBRIDGE, Mass., Oct. 26, 2024 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) – today presented complete results from the Phase 2 IGNAZ study evaluating felzartamab, an investigational anti-CD38 monoclonal antibody, in people living with IgA nephropathy (IgAN). The results showed substantial reductions in proteinuria, stabilization of kidney function, and sustained treatment effect more than 18 months after the last dose of felzartamab. The complete results were shared during an oral presentation at Kidney Week 2024, the American Society of Nephrology's annual meeting, in San Diego, California.

"The complete results of the IGNAZ Study reaffirm our interim findings, showing a reduction in proteinuria, stabilization of kidney function, and sustained treatment effect more than 18 months after the last dose of felzartamab," said Jonathan Barratt, MD, PhD, FRCP, Mayer Professor of Renal Medicine at the University of Leicester. "This is promising news for patients and supports the potential of felzartamab to be a meaningful treatment option for people living with IgA nephropathy, a leading cause of chronic kidney disease."

The Phase 2 IGNAZ study (n=54) explored the efficacy and safety of felzartamab in patients with IgAN and high risk of progressive kidney dysfunction. With respect to efficacy, patients receiving a nine-dose regimen of felzartamab over a six-month treatment period experienced substantial reductions in proteinuria levels as assessed by the urinary protein:creatinine ratio (UPCR) and stabilization of kidney function, as measured by the estimated glomerular filtration rate (eGFR), through 24 months. Notably, patients maintained a mean reduction of approximately 50% in the UPCR through month 24, which was more than 18 months after the last dose was administered. These results suggest that felzartamab may have the potential to preserve kidney function and be administered on treatment cycles instead of continuous dosing.

Further analysis revealed that felzartamab administration resulted in selective and durable reductions in IgA antibody levels, while IgG and IgM levels recovered to baseline 3 months off-treatment. This selective reduction may offer maintenance of significant immune functions essential for infection protection. Overall, administration of felzartamab was generally well tolerated with a safety profile consistent with prior studies.

"We are encouraged by the overall results of the IGNAZ study, especially given the significant unmet medical need for additional treatments to address high-risk IgA nephropathy," said Uptal Patel, M.D., Head of Development, HI-Bio at Biogen. "We are grateful to all the participants, investigators and study staff who contributed to this study, whose findings will help us continue to evaluate felzartamab's role in preserving kidney function as we plan for Phase 3."

About Felzartamab
Felzartamab is an investigational therapeutic human monoclonal antibody directed against CD38, a protein expressed on mature plasma cells. Felzartamab is a potential first-in-class therapeutic candidate with promise as a pipeline-in-a-product across a range of immune-mediated diseases. Felzartamab has been shown in clinical studies to selectively deplete CD38+ plasma cells, which may allow applications that ultimately improve clinical outcomes in a broad range of diseases driven by pathogenic antibodies. Felzartamab was originally developed by MorphoSys AG for multiple myeloma. Human Immunology Biosciences (HI-Bio) exclusively licensed the rights to develop and commercialize felzartamab across all indications in all countries and territories excluding China (including Macau and Hong Kong and Taiwan). Biogen acquired HI-Bio in July 2024.

Felzartamab is an investigational therapeutic candidate that has not yet been approved by any regulatory authority and its safety and effectiveness have not been established.

About IgA Nephropathy (IgAN)
Immunoglobulin A nephropathy (IgAN) is the most common primary glomerulonephritis worldwide. It is a leading cause of chronic kidney disease with up to 40% of IgAN patients progressing to end stage kidney disease about 20 years after diagnosis. IgAN accounts for about 40% of all native-kidney biopsies in Japan, 25% in Europe, 12% in the United States, but less than 5% in central Africa.[1]

About Biogen
Founded in 1978, Biogen is a leading biotechnology company that pioneers innovative science to deliver new medicines to transform patients' lives and to create value for shareholders and our communities. We apply deep understanding of human biology and leverage different modalities to advance first-in-class treatments or therapies that deliver superior outcomes. Our approach is to take bold risks, balanced with return on investment to deliver long-term growth.

We routinely post information that may be important to investors on our website at www.biogen.com. Follow us on social media - Facebook, LinkedIn, X, YouTube.

Biogen Safe Harbor
This news release contains forward-looking statements, including related to the potential clinical effects of felzartamab; the potential benefits, safety and efficacy of felzartamab; the clinical development program for felzartamab; the identification and treatment of IgAN; our research and development program for the treatment of IgAN; the potential of our commercial business and pipeline programs, including felzartamab; 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 our forward-looking statements.

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 including felzartamab; 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 felzartamab; 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; 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 speak only as of the date of this news release.

We do not undertake any obligation to publicly update any forward-looking statements.

References:

1. Rajasekaran et al. (2021) IgA nephropathy: An interesting autoimmune kidney disease. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5198292/. Hastings et al (2018) Clinical Research, Life Expectancy for Patients From the Southeastern United States With IgA Nephropathy. Available at https://www.kireports.org/article /S2468-0249(17)30362-5/fulltext

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