Biogen Initiates Phase 3 Study of Felzartamab for the Treatment of Primary Membranous Nephropathy

June 30, 2025

- Global Phase 3 PROMINENT study will evaluate the efficacy and safety of felzartamab, as compared to tacrolimus, in adults with primary membranous nephropathy (PMN)
- There are currently no therapies specifically approved for PMN, a rare immune-mediated disease affecting the kidneys with an estimated prevalence of ~36k patients in the U.S.[1]
- Felzartamab, an investigational anti-CD38 monoclonal antibody, is a potentially differentiated therapeutic candidate with promise for a broad range of immune-mediated diseases

CAMBRIDGE, Mass., June 30, 2025 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) – announced the initiation of dosing in the global clinical study, PROMINENT. The Phase 3 study will evaluate the efficacy and safety of the investigational drug felzartamab compared to tacrolimus in adults diagnosed with primary membranous nephropathy (PMN). PROMINENT is designed to enroll approximately 180 adults with PMN and expected to readout in 2029. PMN is a severe antibody-mediated disease of the kidney that is a leading cause of nephrotic syndrome and carries a significant risk of kidney failure.

Felzartamab is an anti-CD38 antibody that has been shown in clinical studies to selectively deplete CD38+ cells, including plasma cells, the source of autoantibodies that mistakenly attack the body's own tissues in a range of immune-mediated diseases. Importantly for felzartamab, it is estimated that up to 80% of PMN patients have autoantibodies against PLA2R (aPLA2R) generated by CD38-expressing plasma cells. Currently, there are no approved treatments for PMN and the standard of care includes treatments ranging from immunosuppressants to chemotherapy.[2]

"We are encouraged by the opportunity to advance a Phase 3 study for primary membranous nephropathy, a condition that carries a significant risk of kidney failure," said Travis Murdoch, Head of the Biogen West Coast Hub. "This is the third Phase 3 trial of felzartamab launched by Biogen this year, underscoring our ongoing commitment to developing potential novel treatment options for patients living with kidney disease."

PROMINENT is a 104-week, randomized, open-label, global multicenter Phase 3 trial (NCT06962800) to evaluate the efficacy and safety of felzartamab compared with tacrolimus in moderate- to -high-risk participants with PMN, inclusive of newly diagnosed and relapsed patients, in achieving complete remission of proteinuria. Participants will be randomized to receive either felzartamab or tacrolimus with the primary endpoint being the percentage of participants who achieve complete remissions (CR) at week 104. The study will evaluate both anti-PLA2R (aPLA2R) autoantibody positive and negative patients, stratifying participants based on PLA2R levels. Key secondary endpoints include the impact of felzartamab on serum anti-phospholipase A2 receptor (PLA2R) antibodies and patient-reported outcomes.

"Primary membranous nephropathy remains an unaddressed area of nephrology, for which there are no approved treatments. Felzartamab's mechanism of action designed to deplete the cells that produce the pathogenic antibodies is exciting news for patients that are waiting for potential meaningful new treatment options," said Mohamed El-Shahawy, M.D., MPH, MHA, Director of the Academic Research Institute in Los Angeles, Clinical Professor of Medicine at Keck-University of Southern California School of Medicine, and a principal investigator for the PROMINENT Phase 3 trial. "I'm grateful that Biogen is advancing research in this rare kidney disease and am eager to see the continued progress in the study's enrollment."

Felzartamab was previously investigated in two Phase 2 studies, M-PLACE (n=31) and NewPLACE (n=24), which enrolled patients with aPLA2R-positive PMN. In the final analysis of M-PLACE, reductions in aPLA2R titers were observed in most patients as early as one week (median reduction of 45%), with responses (>50% reduction) in most patients at six months at end-of-treatment. In addition, improvements in proteinuria and serum albumin levels were observed with administration of felzartamab. Across both studies, the majority of treatment emergent adverse events (TEAEs) reported were mild to moderate and consistent with the known mechanism of action of felzartamab in the PMN population. The most common TEAE was infusion-related reactions on the first infusion that were mostly mild to moderate in intensity.

In addition to beginning a Phase 3 study of felzartamab in PMN, Biogen also initiated two other Phase 3 studies of felzartamab this year, TRANSCEND (NCT06685757) for late antibody-mediated rejection in adult kidney transplant recipients and PREVAIL (NCT06935357) in IgA nephropathy.

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 (now MorphoSys GmbH, a Novartis company). 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 Primary Membranous Nephropathy (PMN)
PMN is a severe antibody-mediated disease of the kidney that is a leading cause of nephrotic syndrome and carries a significant risk of kidney failure, with an estimated prevalence of ~36k patients in the United States.[1] Patients with nephrotic syndrome often present with very severe swelling and fatigue related to high-grade proteinuria, and they are also at an increased risk of infection. There are no approved treatments for PMN and the current standard of care includes treatments ranging from immunosuppressants to chemotherapy.[2] Even with these strategies, approximately one third of patients do not achieve remission.[2]

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 press release contains forward-looking statements, relating to: our strategy and plans; potential of, and expectations for the design, timing and results of the PROMINENT study, the ability of felzartamab to treat AMR, PMN or IgAN, our commercial business and pipeline programs; capital allocation and investment strategy; clinical development programs, clinical trials, and data readouts and presentations; regulatory discussions, submissions, filings, and approvals; the potential benefits, safety, our future financial and operating results. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "estimate," "expect," "forecast," "goal," "guidance," "hope," "intend," "may," "objective," "plan," "possible," "potential," "predict," "project," "prospect," "should," "target," "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. Given their forward-looking nature, these statements involve substantial risks and uncertainties that may be based on inaccurate assumptions and could cause actual results to differ materially from those reflected in such statements. These forward-looking statements are based on management's current beliefs and assumptions and on information currently available to management. Given their nature, we cannot assure that any outcome expressed in these forward-looking statements will be realized in whole or in part.

These statements speak only as of the date of this press release and are based on information and estimates available to us at this time. Should known or unknown risks or uncertainties materialize or should underlying assumptions prove inaccurate, actual results could vary materially from past results and those anticipated, estimated or projected. Investors are cautioned not to put undue reliance on forward-looking statements. A further list and description of risks, uncertainties and other matters can be found in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024 and in our subsequent reports on Form 10-Q and Form 10-K, in each case including in the sections thereof captioned "Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in our subsequent reports on Form 8-K. Except as required by law, we do not undertake any obligation to publicly update any forward-looking statements whether as a result of any new information, future events, changed circumstances or otherwise.

References:

1. Based upon Kanigicherla. Nephrol. Dial. Transplant. 2016; McGrogan. Nephrol Dial Transplant. 2011; 36k represents the total number of diagnosed patients who are actively being managed.

2. Dahan et al. (2017) Rituximab for Severe Membranous Nephropathy: A 6-Month Trial with Extended Follow-Up. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5198292/

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