Biogen Highlights the Potential of Felzartamab for a Range of Immune-Mediated Diseases Including Three Phase 3 Programs in Rare Kidney Diseases

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- Felzartamab, an investigational anti-CD38 monoclonal antibody, is a potentially differentiated therapeutic candidate with promise for a broad range of immune-mediated diseases
- Biogen is initiating three pivotal Phase 3 studies of felzartamab across rare kidney indications in 2025, with first readout expected in 2027

Cambridge, Mass. – June 11, 2025 – Biogen Inc. (Nasdaq: BIIB) will host a virtual investor seminar today at 10:00 a.m. ET focused on the potential of the investigational drug felzartamab in rare kidney diseases and the potential to target CD38 for a range of immune-mediated diseases. Since 2023, Biogen has worked to transform its portfolio, building upon its legacy in multiple sclerosis and neuroscience to expand in immunology and rare diseases, where the company has well-established global development commercialization capabilities.

"We have made important progress to support our long-term growth objective, build a strong portfolio with momentum from our recently launched products, and advance an innovative and compelling pipeline," said Christopher A. Viehbacher, President and Chief Executive Officer at Biogen. "We are particularly excited about the addition of felzartamab, which gives us the potential to deliver novel treatments across a range of immune-mediated diseases, beginning with three rare kidney diseases."

Immune-mediated diseases occur when antibodies produced by the immune system mistakenly attack the body's own tissues. These antibodies are produced mainly by plasmablasts and plasma cells that express CD38. Biogen believes that by selectively targeting CD38-expressing plasma cells, the source of these autoantibodies, it may be possible to more precisely modify the disease course in this class of conditions. Felzartamab has been shown in clinical studies to selectively deplete CD38+ cells, including plasma cells and natural killer, or NK, cells and has established proof of concept in three rare kidney diseases. Biogen plans to investigate felzartamab in three Phase 3 pivotal studies, two of which have already been initiated.

Late antibody-mediated rejection (AMR) in kidney transplant recipients
AMR is a leading cause of kidney loss after receiving a transplant. This disease is driven by antibodies to antigens on the donor cells, as well as by damage from natural killer cells that causes microvascular inflammation in the transplanted kidney. Today there are no approved treatment options for AMR.[1]

In a positive Phase 2 study, 82% (n=9/11) of patients who received felzartamab experienced resolution of AMR at week 24, compared to 20% (n=2/10) who received placebo. In patients with late AMR, most adverse events were mild or moderate in severity. Mild or moderate infusion reactions, typically on the first infusion, occurred in patients in the felzartamab group (n=8). There were no treatment-related discontinuations.

Biogen initiated a pivotal global Phase 3 study in AMR, TRANSCEND, in March 2025. This Phase 3 study (NCT06685757) will evaluate the efficacy and safety of felzartamab compared to placebo in adult kidney transplant recipients diagnosed with late antibody-mediated rejection (AMR). TRANSCEND is designed to enroll approximately 120 kidney transplant recipients with late AMR.

In the U.S., felzartamab has received Breakthrough Therapy Designation (BTD) for the treatment of late AMR without T-cell mediated rejection in kidney transplant patients and Orphan Drug Designation (ODD) for development in the treatment of AMR in kidney transplant recipients from the U.S. Food and Drug Administration (FDA). In Europe, felzartamab has received ODD for treatment in solid organ transplantation from the European Medicines Agency (EMA).

Immunoglobulin A nephropathy (IgAN)
IgAN is the most common type of primary glomerulonephritis worldwide. Up to 40% of IgAN patients progress to kidney failure within 20 years after diagnosis, which can lead to the need for dialysis or a kidney transplant.[2] It occurs when an abnormal immunoglobulin protein deposits in the filtering unit (glomerulus) inside the kidneys, leading to inflammation and progressive kidney damage. It is believed that the damage is caused by immune complexes, molecules formed from the binding of antigens to antibodies, which are believed to be produced by CD38 positive plasma cells and plasmablasts. Most patients who get this disease are typically diagnosed in the second and third decade of life and while treatments are available, there is a real need for a novel therapy that provides durable disease remission.

In October 2024, Biogen presented complete and encouraging results from the Phase 2 IGNAZ study (n=54) evaluating felzartamab in people living with IgAN. The results showed reductions in proteinuria levels as assessed by the urinary protein: creatinine ratio (UPCR) and stabilization of kidney function. Notably, patients maintained a mean reduction from baseline of approximately 50% in the UPCR through month 24, which was more than 18 months after the last dose was administered. Overall, administration of felzartamab had a safety profile consistent with prior studies.

Today, Biogen announced the first patient was dosed in the pivotal global Phase 3 study, PREVAIL. The Phase 3 study (NCT06935357) will evaluate the efficacy and safety of felzartamab compared to placebo on proteinuria and preservation of kidney function in adults diagnosed with IgAN. PREVAIL is designed to enroll approximately 454 patients worldwide.

In Europe, felzartamab has received ODD for the treatment of IgAN from the EMA.

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. 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. Importantly for felzartamab, it is estimated that up to 80% of PMN patients have autoantibodies against PLA2R (aPLA2R) generated by CD38-expressing plasma cells. There are no approved treatments for PMN and the current standard of care includes treatments ranging from immunosuppressants to chemotherapy.[3]

Two Phase 2 studies, M-PLACE (n=31) and NewPLACE (n=24), 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.

Biogen plans to initiate dosing in the pivotal global Phase 3 study, PROMINENT, in 2025. The Phase 3 study (NCT06962800) will evaluate the efficacy and safety of felzartamab compared to tacrolimus in adults diagnosed with PMN. PROMINENT is designed to enroll approximately 180 patients worldwide.

In the U.S., felzartamab has received BTD and ODD for development in the treatment of PMN from the FDA.

Potential Indication Expansion
Biogen is evaluating additional expansion indications for felzartamab. Biogen believes the selective targeting of CD38 positive immune cells may provide felzartamab with a potentially differentiated profile across other indications. One example is lupus nephritis (LN), where the company has an ongoing Phase 1 trial. The first data from the LN trial (NCT06064929) is expected in 2026 and will inform the potential for a registrational study.

West Coast Innovation Hub
Biogen obtained felzartamab through the acquisition of Human Immunology Biosciences (HI-Bio) in 2024 as part of the expansion of its immunology portfolio. Biogen established the West Coast Innovation Hub upon the acquisition of HI-Bio. Biogen was able to retain the vast majority of HI-Bio's employees who are now part of this new innovation hub, which is focused on expanding Biogen efforts in immune-mediated diseases.

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An archived version of the webcast and slides, as well as additional video presentations and slides, will also be available.

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 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 relating to: our strategy and plans; potential of, and expectations for, 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, and efficacy of our and our collaboration partners' products and investigational therapies; the anticipated benefits and potential of investments, optimization of the cost structure including our "Fit for Growth" program, actions to improve risk profile and productivity of R&D pipeline, collaborations, and business development activities; intellectual property; litigation and disputes; and 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," "outlook," "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. This presentation and the discussions during this conference call includes, among others, forward-looking statements including: that Biogen is building on a new foundation with the goal of long-term sustainable growth in its commercial portfolio; the multi-billion dollar potential of its late-stage pipeline; that we believe there remains a significant long-term opportunity for our ongoing product launches including LEQEMBI; that we believe that continued execution against these key strategic elements, as well as a disciplined approach to business development, will allow us to generate long-term value for our shareholders by bringing innovative medicines to patients; and all statements and information under the heading "Full Year 2025 Financial Guidance". 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.

We caution that these statements are subject to risks and uncertainties, many of which are outside of our control and could cause future events or results to be materially different from those stated or implied in this document, including, among others, factors relating to: our substantial dependence on revenue from our products and other payments under licensing, collaboration, acquisition or divestiture agreements; uncertainty of long-term success in developing, licensing, or acquiring other product candidates or additional indications for existing products; expectations, plans and prospects relating to product approvals, approvals of additional indications for our existing products, sales, pricing, growth, reimbursement and launch of our marketed and pipeline products; the potential impact of increased product competition in the biopharmaceutical and healthcare industry, as well as any other markets in which we compete, including increased competition from new originator therapies, generics, prodrugs and biosimilars of existing products and products approved under abbreviated regulatory pathways; our ability to effectively implement our corporate strategy; the successful execution of our strategic and growth initiatives, including acquisitions; the drivers for growing our business; difficulties in obtaining and maintaining adequate coverage, pricing, and reimbursement for our products; the drivers for growing our business, including our dependence on collaborators and other third parties for the development, regulatory approval, and commercialization of products and other aspects of our business, which are outside of our full control; risks associated with current and potential future healthcare reforms; risks related to commercialization of biosimilars, which is subject to such risks related to our reliance on third-parties, intellectual property, competitive and market challenges and regulatory compliance; failure to obtain, protect, and enforce our data, intellectual property, and other proprietary rights and the risks and uncertainties relating to intellectual property claims and challenges; the risk that positive results in a clinical trial may not be replicated in subsequent or confirmatory trials or success in early stage clinical trials may not be predictive of results in later stage or large scale clinical trials or trials in other potential indications; risks associated with clinical trials, including our ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates; the occurrence of adverse safety events, restrictions on use with our products, or product liability claims; risks relating to technology, including our incorporation of new technologies such as artificial intelligence into some of our processes; risks related to use of information technology systems and potential impacts of any breakdowns, interruptions, invasions, corruptions, data breaches, destructions and/or other cybersecurity incidents of our systems or those of connected and/or third-party systems; problems with our manufacturing capacity, including our ability to manufacture products efficiently or adequately address global bulk supply risks; risks relating to management, personnel and other organizational changes, including our ability to attracting, retaining and motivating qualified individuals; risks related to the failure to comply with current and new legal and regulatory requirements, including judicial decisions, accounting standards, and tariff or trade restrictions; the risks of doing business internationally, including geopolitical tensions, acts of war and large-scale crises; risks relating to investment in our manufacturing capacity; risks relating to the distribution and sale by third parties of counterfeit or unfit versions of our products; risks relating to the use of social media for our business, results of operations and financial condition; fluctuations in our operating results; risks related to investment in properties; risks relating to access to capital and credit markets to finance our present and future operations and business initiatives and obtain funding for such activities on favorable terms; risks related to indebtedness; the market, interest, and credit risks associated with our investment portfolio; risks relating to share repurchase programs; change in control provisions in certain of our collaboration agreements; fluctuations in our effective tax rate and obligations in various jurisdictions in which we are subject to taxation; environmental risks; and any other risks and uncertainties that are described in other reports we have filed with the U.S. Securities and Exchange Commission.

These statements speak only as of the date of this presentation and the discussions during this conference call 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.

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