Biogen to Highlight Scientific Progress in Rare Kidney Disease at American Society of Nephrology (ASN) Kidney Week 2025

November 3, 2025

- Oral presentation to share first-of-its-kind longitudinal gene expression data in IgA nephropathy, unveiling novel insights into the mechanism of action of felzartamab and advancing the understanding of its disease modifying potential
- Exhibitor Spotlight to discuss role of CD38 cells across a range of immune-mediated kidney diseases
- 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., Nov. 03, 2025 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) – will present new data from its felzartamab clinical development programs at Kidney Week 2025, the American Society of Nephrology's (ASN) annual meeting, taking place November 5-9 in Houston, Texas. Felzartamab, an investigational anti-CD38 monoclonal antibody, is currently being evaluated in three pivotal Phase 3 studies across multiple kidney indications. The first data readout is anticipated in 2027 from TRANSCEND, a study evaluating felzartamab in adult kidney recipients diagnosed with late antibody-mediated rejection (AMR).

"Following the initiation of three pivotal Phase 3 studies in 2025, Kidney Week is a pivotal moment to showcase the potential promise of our anti-CD38 platform to address a range of rare kidney diseases," said Uptal Patel, Head of Biogen West Coast Hub. "We're presenting first-of-its kind gene expression data and evidence of preserved humoral immunity in patients with IgA nephropathy receiving felzartamab, findings that we believe will advance the understanding of this disease and offer meaningful insights to the nephrology community."

Biogen presentations include an oral presentation highlighting new translational RNAseq data from the Phase 2 IGNAZ study on felzartamab treated patients with IgA nephropathy (IgAN). This longitudinal genomic profiling dataset links gene expression changes to felzartamab's mechanism of action in IgAN. A poster presentation evaluates the impact of felzartamab on vaccine immunity in patients with IgAN, indicating that patients with IgAN receiving felzartamab demonstrated preservation of humoral immunity, which may contribute to a favorable safety profile versus other B-cell targeting therapies. In addition, a sponsored Exhibitor Spotlight will educate on the evolving sciences that illustrates a key role for CD38+ cells in immune-mediated kidney diseases, including AMR, IgAN, and primary membranous nephropathy (PMN). Attendees can also explore poster informational presentations on the three ongoing Phase 3 trials of felzartamab.

Biogen ASN Kidney Week 2025 Activities:

- **Oral Presentation:** "Whole Blood RNAseq Profiling Identified Functionally Enriched Gene Expression Patterns in Felzartamab-Treated Patients with IgA Nephropathy: Data from the Phase 2 IGNAZ Study," on Friday, November 7 th at 5:20 p.m. CST
- **Exhibitor Spotlight:** "Role of CD38+ Cells in Immune Mediated Kidney Disease," on Saturday, November 8 th from 12:00 p.m. – 12:45 p.m. CST
- Poster Presentations:
  - "Preservation of Humoral Immunity and Response to Vaccination and Infection in Felzartamab-Treated Patients with IgA Nephropathy: Data From Phase 2 IGANZ Study," on Friday, November 7 th at 10:00 a.m. CST
  - "TRANSCEND, A Phase 3 Trial of the Anti-CD38 Antibody Felzartamab in Kidney Transplant Recipients with Late Antibody-Mediated Rejection," on Thursday, November 6 at 10:00 a.m. CST
  - "TRANSPIRE, A Phase 2 Trial Evaluating the Efficacy and Safety of Felzartamab in Kidney Transplant Recipients with Late Isolated Microvascular Inflammation," on Thursday, November 6 at 10:00 a.m. CST
  - "PREVAIL, A Phase 3 Trial of Felzartamab in Adults with IgA Nephropathy," on Friday, November 7 at 10:00 a.m. CST
  - "PROMINENT, An Open-Label, Randomized Phase 3 Trial of Felzartamab in Primary Membranous Nephropathy," on Friday, November 7 at 10:00 a.m. CST

About Felzartamab
Felzartamab is an investigational therapeutic human monoclonal antibody directed against CD38, a protein expressed on plasma cells, plasmablasts, and natural killer, or NK, 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 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 AMR, IgAN and PMN; our research and development program for the treatment of AMR, IgAN and PMN; 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. 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. 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 differ materially from those stated or implied in this document, including, among others, uncertainty of our long-term success in developing, licensing, or acquiring other product candidates or additional indications for existing products; expectations, plans, prospects and timing of actions 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; 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 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; 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; and the occurrence of adverse safety events, restrictions on use with our products, or product liability claims; and any other risks and uncertainties that are described in reports we have filed with the U.S. Securities and Exchange Commission, which are available on the SEC's website at www.sec.gov.

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. 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.

Digital Media Disclosure
From time to time, we have used, or expect in the future to use, our investor relations website (investors.biogen.com), the Biogen LinkedIn account (linkedin.com/company/biogen) and the Biogen X account (https://x.com/biogen) as a means of disclosing information to the public in a broad, non-exclusionary manner, including for purposes of the SEC's Regulation Fair Disclosure (Reg FD). Accordingly, investors should monitor our investor relations website and these social media channels in addition to our press releases, SEC filings, public conference calls and websites, as the information posted on them could be material to investors.

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