# Biogen Initiates Phase 3 Study of Felzartamab for the Treatment of Late Antibody-Mediated Rejection (AMR) in Kidney Transplant Patients

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- Global Phase 3 TRANSCEND study will evaluate the efficacy and safety of felzartamab, as compared to placebo, in adults with late AMR
- AMR is a leading cause of kidney transplant loss, with approximately ~23k patients living with all forms of AMR in the U.S[1]
- Felzartamab, with demonstrated proof of concept in multiple immune-mediated diseases, represents a key asset in Biogen's late-stage immunology portfolio

CAMBRIDGE, Mass., March 11, 2025 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) – announced the initiation of dosing in the global clinical study, TRANSCEND. The Phase 3 study will evaluate the efficacy and safety of the investigational drug 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.

"Building upon the promising results from the Phase 2 study, which demonstrated felzartamab's first-in-class potential, the launch of the TRANSCEND trial is a crucial milestone in the advancement of its clinical development," said Travis Murdoch, Head of HI-Bio at Biogen. "Losing a kidney after receiving a long-awaited transplant is devastating for the patient and the donor. As we enroll this pivotal Phase 3 trial, we look forward to working in collaboration with medical and patient communities worldwide with the hope of bringing felzartamab forward as potentially the first meaningful treatment option, if approved, for people living with late AMR."

"Antibody-mediated rejection remains a significant challenge in kidney transplantation, with limited safer and effective treatment options currently available. With the potential to be disease-modifying based on the encouraging results observed in the Phase 2 study, I believe felzartamab could be an important new therapeutic treatment option for patients with late AMR," said Suphamai Bunnapradist, M.D., principal investigator of the study and Professor of Clinical Medicine, Director of Research at Connie Frank Kidney Transplant Center, University of California, Los Angeles. "I am pleased to see Biogen enroll the first patient in the Phase 3 TRANSCEND study of felzartamab in AMR and look forward to the trial's continued enrollment."

TRANSCEND is a two-part, 52-week, double-blind, placebo-controlled, multicenter, randomized Phase 3 clinical trial (NCT06685757) to evaluate the efficacy and safety of felzartamab compared with placebo. In Part A, participants will be randomized to receive nine intravenous infusions of felzartamab or placebo over 6 months, and the efficacy and safety of felzartamab compared to placebo will be assessed at 24 weeks. The primary endpoint of TRANSCEND is the percentage of participants who achieve resolution by biopsy of AMR at 6 months. Key secondary endpoints include changes in microvascular inflammation (MVI) score and the percentage of patients achieving an MVI score of zero. MVI is a key histologic feature of AMR and higher MVI scores strongly correlate with reduced kidney allograft survival rates.[2] By targeting CD38, felzartamab is designed to reduce pathogenic antibody producing plasma cells and NK cell activity, addressing key pathophysiologic drivers of MVI and AMR. In Part B, all participants will receive felzartamab for an additional open-label period of 6 months through 52 weeks in order to evaluate longer-term activity, safety and tolerability.

In addition to beginning a Phase 3 study of felzartamab in AMR, as previously announced, Biogen plans to initiate Phase 3 trials of felzartamab in IgA nephropathy and primary membranous nephropathy in 2025. Felzartamab was originally developed by MorphoSys AG (now MorphoSys GmbH, a Novartis company) which was acquired by Novartis in May of 2024. As part of the initiation of the Phase 3 trial for felzartamab, MorphoSys will earn a one-time milestone payment of $35 million from Biogen.

**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 Antibody-Mediated Rejection (AMR) in Kidney Transplant Recipients**
Antibody-mediated rejection (AMR) is a major cause of kidney transplant failure. AMR in kidney transplant is caused by the immune system recognizing the donor kidney as foreign. This can result in antibodies being generated against the donor kidney and potentially leading to its destruction and eventual rejection. AMR demonstrates different properties depending on whether it occurs early (<6 months) or late (>6 months) post-transplantation. Late AMR is associated with a greater risk of graft loss versus early.[3] Effective treatment options for late AMR are currently limited.[4]

**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 TRANSCEND 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:*


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3. Fernando et al. (2023) Early Versus Late Acute AMR in Kidney Transplant Recipients – A Comparison of Treatment Approaches and Outcomes From the ANZDATA Registry. Available at: https://pubmed.ncbi.nlm.nih.gov/37322595/

4. Schinstock et al. (2018) Kidney Transplant with Low Levels of DSA or Low Positive B-Flow Crossmatch: An Underappreciated Option for Highly-Sensitized Transplant Candidates (Page 8). Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5481511/pdf/nihms837168.pdf#page=8; Ciancio et al. 2018 Antibody-Mediated Rejection Implies a Poor Prognosis in Kidney Transplantation: Results From a Single Center. Available at: https://onlinelibrary.wiley.com/doi/10.1111/ctr.13392



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