



Biogen to Present New Data Across Nephrology Portfolio, Including Long-term EMPAVELI® (pegcetacoplan) Phase 3 Results, at American Society of Nephrology (ASN) Kidney Week

October 19, 2026

- Two oral presentations to highlight new 76-week data showing sustained proteinuria reduction and continued eGFR stabilization with a consistent long-term safety profile
- Additional presentations to highlight nephrologist perspectives on gaps in current care practices and limited treatment options for antibody-mediated rejection (AMR)
- Presentations on the role of felzartamab, an investigational anti-CD38 monoclonal antibody, in multiple immune-mediated kidney diseases will also be featured

CAMBRIDGE, Mass., Oct. 19, 2026 (GLOBE NEWSWIRE) -- [Biogen](#) Inc. (Nasdaq: BIIB) will present new EMPAVELI® (pegcetacoplan) data and additional scientific presentations from its nephrology portfolio, including investigational felzartamab, at the American Society of Nephrology (ASN) Kidney Week taking place from October 22 to 25, 2026 in Denver, Colorado.

Key presentations include new EMPAVELI data showing sustained proteinuria reduction and continued estimated glomerular filtration rate (eGFR) stabilization in patients with C3G and primary IC-MPGN over 76 weeks. This data follows the recent U.S. Food and Drug Administration update to expand EMPAVELI's indication to include reducing the loss of kidney function, making it the first and only therapy approved to reduce both proteinuria and the loss of kidney function in adults and adolescents aged 12 years and older with C3G and primary IC-MPGN. Additional presentations on pegcetacoplan and felzartamab will provide insights into the management and understanding of multiple immune-mediated kidney diseases.

"Data shared this week further reinforce EMPAVELI's long-term efficacy and safety profile, while new scientific insights highlight the significant unmet needs and lack of proven therapies in AMR, supporting the potential of felzartamab to address critical gaps in transplant care and other kidney diseases," said Daniel Quirk, MD, Chief Medical Officer at Biogen. "Biogen's current research now spans seven different kidney diseases, and we're proud to share updates on our portfolio's progress with the nephrology community at this premier scientific congress."

Biogen will also be hosting two exhibitor spotlights and 9 poster presentations related to both EMPAVELI and felzartamab. Felzartamab is currently being studied in three Phase 3 trials, TRANSCEND ([NCT06685757](#)) for AMR in adult kidney transplant recipients, PREVAIL ([NCT06935357](#)) in IgA nephropathy, and PROMINENT ([NCT06962800](#)) in primary membranous nephropathy, and a Phase 2 trial in microvascular inflammation ([NCT07219043](#)). Data from the TRANSCEND study is expected in H1 2027.

American Society of Nephrology Congress presentations include:

- **Oral Presentation:** "Pegcetacoplan for 76 weeks maintains proteinuria reduction and eGFR stabilization for pediatric patients: VALIANT+VALE subgroup analysis," on Thursday, October 22 at 4:30 PM MDT.
- **Exhibitor Spotlight:** "Beyond B Cells: Pioneering Plasmablast and Plasma Cell Targeting in Immunoglobulin A Nephropathy and Primary Membranous Nephropathy," on Friday, October 23 at 12:00 PM MDT.
- **Exhibitor Spotlight:** A Treatment for Two Glomerular Diseases: C3G and Primary IC-MPGN on Friday, October 23 at 1:00 PM MDT.
- **Oral Presentation:** "Pegcetacoplan for 76 weeks maintained proteinuria reduction and stabilized kidney function in C3G or primary IC-MPGN," on Saturday, October 24 at 4:30 PM MDT.
- **Poster Presentations:**
 - "TRANSTELLAR: An Open-Label, Long-Term Extension Study of Felzartamab in Participants With Antibody-Mediated Rejection or Microvascular Inflammation," on Thursday, October 22 at 10:00 AM MDT.
 - "Epidemiology of Focal Segmental Glomerulosclerosis: A Systematic Review of Studies Published From 2020 to 2025," on Friday, October 23 at 10:00 AM MDT.
 - "Humanistic Burden of Focal Segmental Glomerulosclerosis: Findings From a Systematic Review," on Friday, October 23 at 10:00 AM MDT.
 - "Nephrologist Perceptions of Unmet Needs in the Treatment of Antibody-Mediated Rejection: Results From a Real-World Survey in Germany and the United States," on Friday, October 23 at 10:00 AM MDT.
 - "Effect of Current Antibody-Mediated Rejection (AMR) Treatments on Microvascular Inflammation (MVI) in Kidney Transplant Recipients: A Rapid Literature Review (RLR) and Meta-Analysis," on Friday, October 23 at 10:00 AM MDT.
 - "Evaluation of Pegcetacoplan in Adults and Adolescents With Focal Segmental Glomerulosclerosis: Rationale and Design of a Sequential Phase 2/3 Study," on Saturday, October 24 at 10:00 AM MDT.
 - "User Experience With Pegcetacoplan On-Body Injector in Patients With C3G or Primary IC-MPGN," on Saturday, October 24 at 10:00 AM MDT.
 - "A Phase 2, Open-Label Trial to Examine Kidney Tissue-Specific Effects of Felzartamab in Adults With IgAN," on Saturday, October 24 at 10:00 AM MDT.
 - "Pharmacokinetic (PK), Pharmacodynamic (PD) and Exposure-Response (E-R) Analysis of Pegcetacoplan in C3 Glomerulopathy (C3G) & Primary Immune-Complex Membranoproliferative Glomerulonephritis (pIC-MPGN)," on Saturday, October 24 at 10:00 AM MDT.

About EMPAVELI® (pegcetacoplan)

EMPAVELI® (pegcetacoplan) is a targeted C3 therapy designed to regulate excessive activation of the complement cascade, part of the body's immune system, which can contribute to the onset and progression of serious diseases.

EMPAVELI is indicated in the United States for the treatment of adult and pediatric patients aged 12 years and older with C3 glomerulopathy (C3G) or primary immune complex membranoproliferative glomerulonephritis (IC-MPGN), to reduce proteinuria and the loss of kidney function. EMPAVELI is also approved for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH).

About C3 Glomerulopathy (C3G) and Primary Immune-Complex Membranoproliferative Glomerulonephritis (IC-MPGN)

C3G and primary IC-MPGN are rare and debilitating kidney diseases that can lead to kidney failure. Excessive C3 deposits are a key marker of disease activity, which can lead to kidney inflammation, damage, and failure. Approximately 50% of people living with C3G and primary IC-MPGN suffer from kidney failure within five to 10 years of diagnosis, requiring a burdensome kidney transplant or lifelong dialysis therapy.¹⁻³ Additionally, approximately 90% of patients who previously received a kidney transplant will experience disease recurrence.⁴

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). Biogen owns exclusive worldwide rights to felzartamab.

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.

U.S. Important Safety Information for EMPAVELI

BOXED WARNING: SERIOUS INFECTIONS CAUSED BY ENCAPSULATED BACTERIA

EMPAVELI, a complement inhibitor, increases the risk of serious infections, especially those caused by encapsulated bacteria, such as *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type B. Life-threatening and fatal infections with encapsulated bacteria have occurred in patients treated with complement inhibitors. These infections may become rapidly life-threatening or fatal if not recognized and treated early.

- **Complete or update vaccination for encapsulated bacteria at least 2 weeks prior to the first dose of EMPAVELI, unless the risks of delaying therapy with EMPAVELI outweigh the risks of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria in patients receiving a complement inhibitor.**
- **Patients receiving EMPAVELI are at increased risk for invasive disease caused by encapsulated bacteria, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious infections and evaluate immediately if infection is suspected.**

Because of the risk of serious infections caused by encapsulated bacteria, EMPAVELI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the EMPAVELI REMS.

CONTRAINDICATIONS

- Hypersensitivity to pegcetacoplan or to any of the excipients
- For initiation in patients with unresolved serious infection caused by encapsulated bacteria including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type B

WARNINGS AND PRECAUTIONS

Serious Infections Caused by Encapsulated Bacteria

EMPAVELI, a complement inhibitor, increases a patient's susceptibility to serious, life-threatening, or fatal infections caused by encapsulated bacteria including *Streptococcus pneumoniae*, *Neisseria meningitidis* (caused by any serogroup, including non-groupable strains), and *Haemophilus influenzae* type B. Life-threatening and fatal infections with encapsulated bacteria have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors. The initiation of EMPAVELI treatment is contraindicated in patients with unresolved serious infection caused by encapsulated bacteria.

Complete or update vaccination against encapsulated bacteria at least 2 weeks prior to administration of the first dose of EMPAVELI, according to the most current ACIP recommendations for patients receiving a complement inhibitor. Revaccinate patients in accordance with ACIP recommendations considering the duration of therapy with EMPAVELI. Note that ACIP recommends an administration schedule in patients receiving complement inhibitors that differs from the administration schedule in the vaccine prescribing information. If urgent EMPAVELI therapy is indicated in a patient who is not up to date with vaccines against encapsulated bacteria according to ACIP recommendations, provide the patient with antibacterial drug prophylaxis and administer these vaccines as soon as possible. The benefits and risks of treatment with EMPAVELI, as well as the benefits and risks of antibacterial drug prophylaxis in unvaccinated or vaccinated patients, must be considered against the known risks for serious infections caused by encapsulated bacteria.

Vaccination does not eliminate the risk of serious encapsulated bacterial infections, despite development of antibodies following vaccination. Closely monitor patients for early signs and symptoms of serious infection and evaluate patients immediately if an infection is suspected. Inform patients of these signs and symptoms and instruct patients to seek immediate medical care if these signs and symptoms occur. Promptly treat known infections. Serious infection may become rapidly life-threatening or fatal if not recognized and treated early. Consider interruption of EMPAVELI in patients who are undergoing treatment for serious infections.

EMPAVELI is available only through a restricted program under a REMS.

EMPAVELI REMS

EMPAVELI is available only through a restricted program under a REMS called EMPAVELI REMS, because of the risk of serious infections caused by

encapsulated bacteria. Notable requirements of the EMPAVELI REMS include the following:

Under the EMPAVELI REMS, prescribers must enroll in the program. Prescribers must counsel patients about the risks, signs, and symptoms of serious infections caused by encapsulated bacteria, provide patients with the REMS educational materials, ensure patients are vaccinated against encapsulated bacteria at least 2 weeks prior to the first dose of EMPAVELI, prescribe antibacterial drug prophylaxis if patients' vaccine status is not up to date and treatment must be started urgently, and provide instructions to always carry the Patient Safety Card both during treatment, as well as for 2 months following last dose of EMPAVELI. Pharmacies that dispense EMPAVELI must be certified in the EMPAVELI REMS and must verify prescribers are certified.

Further information is available at www.empavelirems.com or 1-888-343-7073.

Infusion-Related Reactions

Systemic hypersensitivity reactions (e.g., facial swelling, rash, urticaria, pyrexia) have occurred in patients treated with EMPAVELI, which may resolve after treatment with antihistamines. Cases of anaphylaxis leading to treatment discontinuation have been reported. If a severe hypersensitivity reaction (including anaphylaxis) occurs, discontinue EMPAVELI infusion immediately, institute appropriate treatment, per standard of care, and monitor until signs and symptoms are resolved.

Interference with Laboratory Tests

There may be interference between silica reagents in coagulation panels and EMPAVELI that results in artificially prolonged activated partial thromboplastin time (aPTT); therefore, avoid the use of silica reagents in coagulation panels.

ADVERSE REACTIONS

Most common adverse reactions in adult and pediatric patients 12 years of age and older with C3G or primary IC-MPGN (incidence $\geq 10\%$) were infusion-site reactions, pyrexia, nasopharyngitis, influenza, cough, and nausea.

USE IN SPECIFIC POPULATIONS

Females of Reproductive Potential

EMPAVELI may cause embryo-fetal harm when administered to pregnant women. Pregnancy testing is recommended for females of reproductive potential prior to treatment with EMPAVELI. Advise female patients of reproductive potential to use effective contraception during treatment with EMPAVELI and for 40 days after the last dose.

Please see full [Prescribing Information](#), including **Boxed WARNING** regarding serious infections caused by encapsulated bacteria, and [Medication Guide](#).

About the Sobi® and Apellis (now part of Biogen) Collaboration

Apellis (now part of Biogen) and Sobi have global co-development rights for systemic pegcetacoplan. Sobi has exclusive ex-U.S. commercialization rights for systemic pegcetacoplan. Apellis (now part of Biogen) has exclusive U.S. commercialization rights for systemic pegcetacoplan and worldwide commercial rights for ophthalmological pegcetacoplan, including for geographic atrophy.

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, relating to, among others, the potential clinical effects of EMPAVELI and felzartamab; the potential benefits, safety and efficacy of EMPAVELI in patients with C3G or Primary IC-MPGN and of felzartamab in late antibody-mediated rejection in adult kidney transplant recipients, and in patients with IgAN, primary membranous nephropathy, and microvascular inflammation; the clinical development programs for EMPAVELI and felzartamab; advancing our anti-CD38 platform and our nephrology research and development programs; the potential of our commercial business and pipeline programs, including EMPAVELI and felzartamab; potential of, and expectations for the design, timing and results of our clinical trial programs, including the long-term EMPAVELI Phase 3 results, as well as the TRANSCEND, PREVAIL and PROMINENT studies; and risks and uncertainties associated with drug development and commercialization. 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" or the negative of these words or 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. 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 other 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, 2025 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-](https://www.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.

References:

1. Smith RJH, et al. Nat Rev Nephrol. 2019;15(3):129-143.
2. Servais A, et al. Kidney Int. 2012;82(4):454-464.
3. Zand L, et al. J Am Soc Nephrol. 2014;25(5):1110-1117.
4. Tarragón, B, et al. C3 Glomerulopathy Recurs Early after Kidney Transplantation in Serial Biopsies Performed within the First 2 Years after Transplantation. Clinical Journal of the American Society of Nephrology. August 2024; 19(8)1005-1015.

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