Biogen Announces Upcoming Kidney Presentations at European Renal Association and American Transplant Congresses

June 3, 2026

- Data presentations across multiple kidney diseases illustrate the breadth of Biogen's nephrology portfolio with EMPAVELI® (pegcetacoplan) and felzartamab, an investigational anti-CD38 monoclonal antibody.

CAMBRIDGE, Mass., June 03, 2026 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) announced that fourteen abstracts highlighting data from its nephrology portfolio, including EMPAVELI® (pegcetacoplan) and investigational felzartamab, have been accepted for presentation at the 63rd European Renal Association Congress (ERA) and the 2026 American Transplant Congress (ATC).

"Our presence across two key medical congresses highlights the momentum of our newly broadened nephrology portfolio, which now includes EMPAVELI® (pegcetacoplan) in addition to the multiple Phase 3 studies of felzartamab," said Daniel Quirk, MD, Chief Medical Officer at Biogen. "We look forward to continuing to advance the science and development across a spectrum of kidney diseases, with the goal of helping to bring meaningful progress to patients."

At ERA, taking place June 3-6 in Glasgow, Scotland, presentations include new post-hoc analyses from the pivotal Phase 3 VALIANT study for EMPAVELI and its long-term extension VALE study showing the sustained efficacy and safety profile of EMPAVELI over one year in patients with C3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN). Presentations of EMPAVELI will be made in collaboration with Sobi, which retains commercial rights to EMPAVELI® (Aspaveli® in the EU) outside the U.S.

At ATC, taking place June 20-24 in Boston, Massachusetts, additional analyses of the Phase 2 felzartamab trial in antibody-mediated rejection (AMR) assess the impact of the investigational treatment on patients with long-standing rejection history and different forms of previous rejection treatment. A sponsored Symposium will educate on emerging biomarkers for early identification and monitoring of transplant rejection and illustrate the role of CD38+ cells in AMR and microvascular inflammation (MVI). Additionally, a presentation on EMPAVELI will share pooled data from two studies assessing treatment in post transplant patients with recurrent C3G or primary IC-MPGN.

European Renal Association Congress presentations include:

- **Oral Presentation:** "Pegcetacoplan treatment response in VALIANT/VALE: Impact of disease chronicity in C3G and primary IC-MPGN," on Thursday, June 4th at 9:21 a.m. BST
- **Oral Presentation:** "Pegcetacoplan sustained clinical benefit in C3G and primary IC-MPGN through 1 year of therapy: Data from VALIANT/VALE," on Thursday, June 4th at 11:27 a.m. BST
- **Oral Presentation:** "Pegcetacoplan treatment response in VALIANT/VALE: Impact of genetic and acquired complement dysregulation and disease type in C3G and primary IC-MPGN," on Thursday, June 4th at 12:09 p.m. BST
- **Oral Presentation:** "Real-world clinical profile, treatment patterns and outcomes associated with C3G and primary IC-MPGN: insights from the UK RaDaR registry," on Thursday, June 4th at 12:21 p.m. BST
- **Oral Presentation:** "Investigating the Effects of Felzartamab Treatment on Peripheral Blood Transcriptomes in Patients with Chronic Antibody-mediated Rejection," on Thursday, June 4th at 12:33 p.m. BST
- **Oral Presentation:** "Safety and low incidence of meningococcal infections with pegcetacoplan in C3G / primary IC-MPGN and PNH," on Thursday, June 4th at 3:27 p.m. BST
- **Oral Presentation:** "Evaluation of pegcetacoplan in adults and adolescents with focal segmental glomerulosclerosis: Rationale and design of a sequential phase 2/3 study," on Thursday, June 4th at 4:24 p.m. BST
- **Oral Presentation:** "Decreasing rates of injection site reactions over time: Long-term outcomes across multiple indications support pegcetacoplan for C3G/primary IC-MPGN," on Friday, June 5th at 9:03 a.m. BST
- **Oral Presentation:** "Prolonged CD38 Targeting with Felzartamab Achieves Sustained Suppression of Antibody-mediated Rejection: Biomarker-guided Open-label Phase 2 Extension," on Friday, June 5th at 9:27 a.m. BST
- **Oral Presentation:** "Soluble BCMA as a Biomarker of CD38+ Plasma Cell Depletion in Felzartamab-Treated Patients With IgA Nephropathy From the Phase 2 IGNAZ Study," on Friday, June 5th at 4:24 p.m. BST
- Poster Presentations:
  - Pegcetacoplan population pharmacokinetics and exposure-response analysis in adolescent and adult patients with C3G or primary IC-MPGN on Friday, June 5th at 6:15 p.m. BST
  - Epidemiology of C3G and primary IC-MPGN: a systematic literature review and meta-analysis on Friday, June 5th at 6:15 p.m. BST

American Transplant Congress presentations include:

- **Symposium:** "Advancements in Antibody-Mediated Rejection and Microvascular Inflammation of Kidney Allograft: Biology, Biomarkers, and Beyond," on Tuesday, June 23rd from 12:15 p.m. – 1:15 p.m. EDT

- **Oral Presentation:** “Felzartamab, an anti-CD38 antibody, in late AMR: efficacy independent of prior rejection history or therapy “on Monday, June 22nd at 11:15 a.m. EDT
- **Oral Presentation:** “Effects of felzartamab on Digital Cytometry Leukocyte Estimates in Biopsies with ABMR,” on Sunday, June 21st at 3:45 p.m. EDT
- **Oral Presentation:** “Pegcetacoplan for Posttransplant Patients with Complement 3 Glomerulopathy or Primary (Idiopathic) Immune-Complex membranoproliferative Glomerulonephritis,” on Sunday, June 21st at 3:45 p.m. EDT
- Poster Presentations:
  - Late breaking poster**:** “Felzartamab for antibody mediated rejection: a phase 2 open label extension study,” on Saturday, June 20th at 5:45 p.m. EDT
  - “Establishing a central pathology review process and adjudication framework to standardize biopsy-based endpoints in transplant clinical trials” on Saturday, June 20th at 5:45 p.m. EDT
  - “TRANSCEND and TRANSPIRE: phase 3 and 2 trials of the anti-CD38 antibody felzartamab in kidney transplant recipients with antibody medical rejection or isolated microvascular inflammation,” on Monday, June 22nd at 2:45 p.m. EDT
  - “Monitoring anti-CD38 treatment with felzartamab in antibody mediated kidney allograft rejection,” on Monday, June 22nd at 2:45 p.m. EDT
  - “Effect of the anti-CD38 antibody felzartamab on Natural Killer cells” on Monday, June 22nd at 2:45 p.m. EDT

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.

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.[1] Effective treatment options for late AMR are currently limited.[2]

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.[3-5] Additionally, approximately 90% of patients who previously received a kidney transplant will experience disease recurrence.[6]

About the VALIANT Study
The VALIANT Phase 3 study (NCT05067127) was a randomized, placebo-controlled, double-blinded, multi-center study that evaluated EMPAVELI® (pegcetacoplan) efficacy and safety in 124 patients who were 12 years of age and older with C3G or primary IC-MPGN. It is the largest single trial conducted in these populations and the only study to include pediatric and adult patients, with native and post-transplant kidneys. Study participants were randomized to receive EMPAVELI or placebo twice weekly for 26 weeks. Following this 26-week randomized controlled period, patients were able to proceed to a 26-week open-label phase in which all patients received EMPAVELI. The primary endpoint of the study was the log transformed ratio of urine protein-to-creatinine ratio (UPCR) at Week 26 compared to baseline.

About Empaveli (pegcetacoplan)
Empaveli (pegcetacoplan) is a targeted C3 and C3b therapy designed to regulate excessive activation of the complement cascade, part of the body’s immune system, which can lead to the onset and progression of many serious diseases. It is the first treatment approved in the United States for C3 glomerulopathy (C3G) or primary immune complex membranoproliferative glomerulonephritis (IC-MPGN) in patients 12 years of age and older, to reduce proteinuria. Empaveli is also approved for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH) in the United States, European Union, and other countries globally, and is under investigation for other rare diseases.

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 (eg, 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 ≥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 and Sobi have global co-development rights for systemic pegcetacoplan. Sobi has exclusive ex-U.S. commercialization rights for systemic pegcetacoplan. Apellis 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 benefits, safety and efficacy of EMPAVELI and felzartamab; the potential of felzartamab to be an important option in addressing the effects of AMR and MVI; the potential of Biogen's commercial business and pipeline programs, including EMPAVELI and felzartamab; potential regulatory discussions, submissions and approvals and the timing thereof; and the 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-) 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. 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/
2. 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
3. Smith RJH, et al. Nat Rev Nephrol. 2019;15(3):129-143.
4. Servais A, et al. Kidney Int. 2012;82(4):454-464.
5. Zand L, et al. J Am Soc Nephrol. 2014;25(5):1110-1117.
6. 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.

MEDIA CONTACT:
Biogen
Madeleine Shin
+ 1 781 464 3260
public.affairs@biogen.com

INVESTOR CONTACT:
Biogen
Tim Power
+1 781 464 2442
IR@biogen.com