Phase 3 Pediatric EMPAVELI Data Published in Clinical Journal of the American Society of Nephrology Show Reduction in Proteinuria and Stabilized Kidney Function in Adolescents with C3G or Primary IC-MPGN

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- *EMPAVELI-treated adolescents achieved a 75% relative reduction in proteinuria within 6 months versus placebo*
- *EMPAVELI is the only approved treatment for adolescents with C3G and primary IC-MPGN, based on VALIANT study*
- *Publication follows a recent FDA label update to expand EMPAVELI's indication to include reducing the loss of kidney function in patients 12 years and older, in addition to reducing proteinuria*

CAMBRIDGE, Mass., Sept. 17, 2026 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced the publication of results from a prespecified adolescent subgroup analysis of the Phase 3 VALIANT study evaluating EMPAVELI® (pegcetacoplan) in the *Clinical Journal of the American Society of Nephrology* (CJASN). The dedicated subgroup analysis was first presented at the 2025 Annual Meeting of the European Society of Paediatric Nephrology (ESPN).

"C3G and primary IC-MPGN are often diagnosed early in life, when preventing progressive kidney damage can have a meaningful long-term impact," said Bradley Dixon, M.D., Section Chief of Pediatric Nephrology and Professor of Pediatrics, University of Colorado School of Medicine and Children's Hospital Colorado. "The VALIANT results show substantial reductions in proteinuria and stabilization of kidney function in adolescents, consistent with what we observed in the broader population. These findings are especially encouraging for young patients who may otherwise face a lifetime of progressive kidney disease leading to a potential kidney transplant."

The analysis showed that a cohort of adolescents aged 12 to 17 years with C3 glomerulopathy (C3G) or primary immune complex membranoproliferative glomerulonephritis (IC-MPGN) treated with EMPAVELI achieved clinically meaningful reductions in proteinuria and stabilization of kidney function compared with placebo. The findings were consistent with results from the overall VALIANT population.

Adolescents represented nearly half of the VALIANT study population, providing one of the largest randomized datasets in this age group for C3G and primary IC-MPGN.

Among the adolescent cohort (n= 55) at Week 26, results included:

- EMPAVELI-treated adolescents achieved a 75% relative reduction in proteinuria versus placebo (95% CI: 59%-84%; nominal p<0.001), with reductions observed as early as Week 4 and continuing through Week 26.
- 71% of adolescents treated with EMPAVELI achieved at least a 50% reduction in proteinuria, compared with 4% receiving placebo (nominal p<0.001).
- 57% of EMPAVELI-treated adolescents achieved both stable kidney function and at least a 50% reduction in proteinuria, compared with 4% receiving placebo (nominal p=0.002).

The publication follows the recent FDA-approved label expansion for EMPAVELI, 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. The label update was based on 52-week efficacy and safety data from the VALIANT study demonstrating substantial reductions in proteinuria and sustained preservation of kidney function, as measured by estimated glomerular filtration rate (eGFR).

"The results published in the Clinical Journal of the American Society of Nephrology further strengthen our confidence in the benefits EMPAVELI can provide for adolescents living with C3G and primary IC-MPGN," said Daniel Jones, Ph.D., Vice President, Head of Global Medical Affairs for EMPAVELI at Biogen. "Together with the recent expansion of the U.S. indication for EMPAVELI, these findings reinforce the potential for EMPAVELI to help protect patients' kidney health."

EMPAVELI was well tolerated in adolescents, with a safety profile consistent with the overall VALIANT population.

About the VALIANT Study

VALIANT (NCT05067127) was a randomized, placebo-controlled, double-blind, multicenter Phase 3 study evaluating the efficacy and safety of EMPAVELI in 124 patients aged 12 years and older with C3G or primary IC-MPGN.

The trial included both adolescent and adult patients with native kidney disease or post-transplant disease recurrence. Participants were randomized to receive EMPAVELI or placebo twice weekly for 26 weeks, followed by a 26-week open-label period in which all patients received EMPAVELI. The primary endpoint was the change in urine protein-to-creatinine ratio (UPCR) at Week 26 compared with baseline.

About C3 Glomerulopathy and Primary IC-MPGN

C3G and primary IC-MPGN are rare, chronic, complement-mediated kidney diseases that can lead to progressive kidney damage and kidney failure.

The diseases frequently begin early in life. Approximately half of patients with C3G are diagnosed before age 18, while the median age at diagnosis for primary IC-MPGN is approximately 21 years. Despite standard-of-care treatment, approximately 20% of children with C3G or primary IC-MPGN progress to kidney failure within 10 to 15 years of diagnosis.

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).

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 ≥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 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, Instagram, LinkedIn, X, YouTube.

Biogen Safe Harbor

This news release contains forward-looking statements, relating to, among others, the potential clinical effects of EMPAVELI; the potential benefits, safety and efficacy of EMPAVELI in adolescents with C3G or Primary IC-MPGN; the clinical development program for EMPAVELI; advancing C3G and Primary IC-MPGN research and the treatment of C3G and Primary IC-MPGN; our research and development programs for the treatment of C3G and Primary IC-MPGN; the potential of our commercial business and pipeline programs, including EMPAVELI; 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-) 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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