Akebia Therapeutics Announces First Patient Dosed in Phase 2 Clinical Trial of Praliciguat for the Treatment of Focal Segmental Glomerulosclerosis (FSGS)

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Clinical trial evaluating changes in urine protein-to-creatinine ratio, a widely-accepted endpoint measuring risk reduction of kidney failure

CAMBRIDGE, Mass., Jan. 06, 2026 (GLOBE NEWSWIRE) -- Akebia Therapeutics®, Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease, today announced that the first patient has been dosed in a Phase 2 clinical trial of praliciguat, an oral, once-daily soluble guanylate cyclase (sGC) stimulator being evaluated for the treatment of biopsy-confirmed FSGS, a rare kidney disease, with plans to assess its use in other rare podocytopathies in the future.

“We are pleased by the timely initiation of this important Phase 2 clinical trial of praliciguat and have successfully dosed the first patient following the defined screening process,” said Dr. Steven K. Burke, Chief Medical Officer. “FSGS is a rare kidney disease that affects approximately 40,000 patients in the U.S, and there are no approved treatments. Praliciguat is a promising therapeutic candidate with no significant safety issues observed in Phase 1 studies in healthy volunteers and Phase 2 studies in heart failure and diabetic kidney disease. Praliciguat is a key component of our recently announced mid-stage rare kidney disease pipeline.”

The Phase 2, randomized, double-blind, placebo-controlled, multicenter study is designed to evaluate the efficacy and safety of praliciguat in adults with biopsy-confirmed FSGS. Approximately 60 patients who are already receiving maximally tolerated doses of an angiotensin-converting enzyme inhibitor (ACEi) or an angiotensin receptor blocker (ARB) will be randomized 1:1 to receive praliciguat or placebo for an initial 24-week treatment period. Following this double-blind period, all participants will receive praliciguat in the open-label portion of the study for an additional 24 weeks. The primary endpoint is defined as change from baseline in urine protein-to-creatinine ratio (UPCR) measured at Week 24. The secondary endpoint is defined as the percentage of patients with partial remission at Week 24 (measured as a 40% UPCR reduction and UPCR<1.5 gram/gram). More information about this study, can be found here.

About Praliciguat
Akebia licensed praliciguat from Cyclerion Therapeutics, Inc. No significant safety issues were observed with praliciguat in Phase 1 studies in healthy volunteers and Phase 2 studies in heart failure and diabetic kidney disease. Praliciguat adverse events were infrequent and consistent with its known blood pressure lowering effect.

About Akebia Therapeutics
Akebia Therapeutics, Inc. is a fully integrated biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease. Akebia was founded in 2007 and is headquartered in Cambridge, Massachusetts. For more information, please visit our website at www.akebia.com, which does not form a part of this release.

Forward-Looking Statements
Statements in this press release regarding Akebia Therapeutics, Inc.'s ("Akebia's") strategy, plans, prospects, expectations, beliefs, intentions and goals are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, and include, but are not limited to, statements regarding: Akebia’s plans and expectations with respect to its Phase 2 clinical trial of praliciguat, including its use in other rare podocytopathies and timing thereof; Akebia’s beliefs and statements with respect to FSGS, including the number of U.S. patients and that there are no approved treatments; Akebia’s plans and expectations with respect to praliciguat, including that is a promising therapeutic candidate with no significant safety issues observed in Phase 1 studies in healthy volunteers and Phase 2 studies in heart failure and diabetic kidney disease and that it is a key component in its mid-stage kidney disease pipeline. The terms "intend," "believe," "plan," "goal," "potential," "anticipate, "estimate," "expect," "future," "will," "continue," derivatives of these words, and similar references are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results, performance or experience may differ materially from those expressed or implied by any forward-looking statement as a result of various risks, uncertainties and other factors, including, but not limited to, risks associated with: the potential therapeutic benefits, safety profile, and effectiveness of Vafseo and Akebia’s development candidates; the results of preclinical and clinical research; Akebia’s ability to enroll patients in its clinical trials; decisions made by health authorities, such as the FDA, with respect to regulatory filings and other interactions; the potential demand and market potential and acceptance of, as well as coverage and reimbursement related to, Vafseo®, including estimates regarding the potential market opportunity; the competitive landscape for Auryxia® and Vafseo, including generic entrants and the timing thereof; the ability of Akebia to attract and retain qualified personnel; Akebia's ability to achieve and maintain profitability and to maintain operating expenses consistent with its operating plan; manufacturing, supply chain and quality matters and any recalls, write-downs, impairments or other related consequences or potential consequences; early termination of any of Akebia's collaborations; and changes in the geopolitical environment and uncertainty surrounding U.S. trade policy on tariffs. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, and other filings that Akebia may make with the U.S. Securities and Exchange Commission in the future. These forward-looking statements (except as otherwise noted) speak only as of the date of this press release, and, except as required by law, Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this press release.

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