Akebia Therapeutics Announces First Participants Dosed in Phase 1 Clinical Trial of AKB-9090

April 13, 2026

AKB-9090 is being evaluated as a potential treatment for cardiac surgery-associated acute kidney injury

CAMBRIDGE, Mass., April 13, 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 the first participants have been dosed in a Phase 1 clinical trial of AKB-9090, an internally developed hypoxia-inducible factor-prolyl hydroxylase (HIF-PH) inhibitor being evaluated for the treatment of cardiac surgery-associated acute kidney injury (AKI). The Phase 1 randomized, double-blind, placebo-controlled, single and multiple ascending dose (SAD/MAD) study is designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of AKB-9090 administered intravenously in healthy adult participants.

“AKB-9090 has been internally developed leveraging our team’s extensive expertise in HIF-PH biology, and we believe is a promising product candidate with the potential to treat acute care conditions with significant unmet need such as AKI,” said John P. Butler, Chief Executive Officer of Akebia. “We are pleased to have dosed our first study participants in the Phase 1 clinical trial and plan to report top line data in early 2027.”

The trial will enroll up to 70 participants randomized to receive either AKB-9090 or placebo across sequential single and multiple dose-escalation cohorts. The primary endpoints include the incidence of treatment-emergent adverse events and changes in clinical laboratory parameters, vital signs, and electrocardiograms. More information about this study can be found here.

In late 2025, Akebia introduced its pipeline of clinical stage kidney disease programs. In addition to AKB-9090, Akebia is evaluating praliciguat, a soluble guanylate cyclase stimulator, currently in a Phase 2 clinical trial targeting focal segmental glomerulosclerosis; and AKB-097, a next-generation tissue-targeted complement inhibitor planned to enter a Phase 2 basket trial in rare kidney diseases, including IgA nephropathy, lupus nephritis and C3 glomerulopathy, in the second half of 2026.

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 presentation 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, strategies and prospects for its business; Akebia’s beliefs and expectations regarding the mechanism of action of its technologies’ and ability to address the biological need of certain diseases; Akebia’s plans and expectations with respect to AKB-9090, including the timing of the completion of the current Phase 1 trial, the number of patients to be enrolled in the trial, the timing of reporting top line data from the trial, and the indication to be evaluated, and AKB-9090’s potential for successful development and regulatory path to treat acute care conditions with significant unmet need, including AKI; Akebia’s plans and expectations with respect to praliciguat and the Phase 2 trial; and Akebia’s plans and expectations with respect to AKB-097, including the timing of initiation of an open label Phase 2 basket study and the indications to be evaluated. The terms "intend," "believe," "plan," "goal," "potential," "anticipate," "estimate," "expect," "future," "will," "continue," “could,” 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 initiate and 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 Auryxia® and 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 Annual Report on Form 10-K for the year ended December 31, 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 presentation, and, except as required by law, Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this presentation.

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