Akebia Therapeutics Announces Initiation of a Phase 2 Basket Trial to Study Ebribafusp, a Next-Generation Complement Inhibitor in Rare Kidney Diseases

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The open-label Phase 2 trial will evaluate ebribafusp for the treatment of IgA nephropathy, lupus nephritis and C3 glomerulopathy

CAMBRIDGE, Mass., Aug. 03, 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 initiation of a Phase 2 basket trial to evaluate the safety, efficacy, and pharmacokinetics of ebribafusp for the treatment of rare complement-mediated kidney diseases, including IgA nephropathy (IgAN), lupus nephritis (LN), and C3 glomerulopathy (C3G). Ebribafusp (previously referred to as AKB-097 and ADX-097) is an anti-C3d factor H fusion protein designed to inhibit complement activation in tissues without inhibiting the complement system in the blood.

“There are over 200,000 patients in the United States alone living with rare complement-mediated kidney diseases, including IgAN, LN and C3G, in which complement inhibitors have shown therapeutic potential,” said Dr. Steven Burke, Chief R&D and Medical Officer at Akebia. “The goal of the Phase 2 basket trial is to demonstrate the safety, efficacy, and pharmacokinetics of weekly subcutaneous dosing of ebribafusp in reducing complement activation in the kidney without inhibiting the complement system in the blood. If successful, we believe this may provide a safer and more effective long-term treatment option for patients and reduce the risk of serious bacterial infections.”

The Phase 2 basket trial is expected to enroll up to 30 patients with IgAN, LN or C3G. Patients will receive ebribafusp dosed once-weekly subcutaneously for 26 weeks in the main study followed by a long-term extension study for responders. The primary endpoint is the incidence of adverse events, and secondary endpoints include the change in proteinuria measured by urine protein creatinine ratio (UPCR), kidney function measured by estimated glomerular filtration rate (eGFR), and pharmacokinetics. In addition, the trial will measure blood and urine complement biomarkers to determine if ebribafusp reduces complement activity in kidney tissue while avoiding inhibition of the complement system in the blood. In a Phase 1 study in healthy participants, weekly 450 mg subcutaneous dosing met desired exposures for predicted complement inhibition in tissues without inhibiting complement in the blood.

The Phase 2 basket trial is open-label, and Akebia expects to report initial data in 2027. Additional information about the trial is available at ClinicalTrials.gov under identifier NCT06419205.

About Ebribafusp
Ebribafusp (previously referred to as AKB-097 and ADX-097), an anti-C3d factor H fusion protein, is an investigational, next generation complement inhibitor. The presence of C3d in glomeruli is a hallmark of numerous complement-mediated kidney diseases. Ebribafusp is designed to target the sites of complement activation in tissues to degrade the alternative pathway C3 convertase. Ebribafusp has the potential to localize to the affected glomeruli, which have significant deposits of C3d, while avoiding complement inhibition in the blood.

In November 2025, Akebia acquired the global rights to ebribafusp from Q32 Bio, Inc. (Q32 Bio). In nonclinical studies conducted by Q32 Bio, ebribafusp distributed to affected tissues and organs and demonstrated durable tissue pharmacokinetic and pharmacodynamic properties. In a completed Phase 1 clinical trial in healthy volunteers conducted by Q32 Bio, Ebribafusp was observed to be generally well-tolerated and demonstrated minimal anti-drug antibodies.

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: Akebia’s beliefs and expectations regarding the potential benefits and mechanism of action of ebribafusp, including its potential to inhibit complement activation in tissues, including localizing to affected glomeruli that have significant deposits of C3d, without inhibiting the complement system in the blood; Akebia’s beliefs that if ebribafusp successfully reduces complement activation in the kidney without inhibiting the complement system in the blood, it may provide a safer and more effective long-term treatment option for patients and reduce the risk of serious bacterial infections; Akebia’s beliefs regarding the therapeutic potential of complement inhibitors for patients with rare complement-mediated kidney diseases; and Akebia’s goals and expectations regarding the Phase 2 basket trial, including its ability to demonstrate safety, efficacy and pharmacokinetics, the number of patients to be enrolled and the timing thereof, and the timing of reporting initial data from the trial.

The terms "intend," "believe," "plan," "goal," "potential," "anticipate," "estimate," “target,” “predict,” "expect," "future," “may,” "will," “could,” "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 Akebia’s products and product candidates; risks and uncertainties related to Akebia’s ongoing

and planned research and development activities, including initiating, conducting or completing preclinical studies and clinical trials, the ability to enroll patients in and the timing of such preclinical studies and clinical trials; the results of Akebia's preclinical studies and clinical trials, including that initial, preliminary, interim or retrospective data, analysis or results may not be replicated in, or predictive of, final analyses or results of future preclinical or clinical data, analyses or results or that such analysis or results may not support further development of such product candidates; 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 Akebia's commercial products, including estimates regarding the potential market opportunity; the competitive landscape for Akebia's commercial products, including generic entrants and the timing thereof; Akebia's ability to obtain and maintain patent protection on its products and product candidates, and to successfully defend these patents against third-party challenges; Akebia's ability to attract and retain qualified personnel; Akebia's ability to achieve and maintain profitability and to maintain operating expenses consistent with its operating plan; Akebia's revenue and that its financial results from prior periods may not be indicative of future results; 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 most recent Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission (SEC), and other filings that Akebia may make with the SEC 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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