KALA BIO Announces Topline Results from CHASE Phase 2b Clinical Trial Evaluating KPI-012 for the Treatment of Persistent Corneal Epithelial Defect (PCED) Did Not Meet Primary Endpoint

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-- Study did not meet primary endpoint of complete healing of PCED at Week 8; secondary endpoints also did not achieve statistical significance --

-- KPI-012 was well-tolerated with no treatment-related serious adverse events observed --

-- KALA to cease clinical development of KPI-012, preserve cash and explore strategic options --

ARLINGTON, Mass., Sept. 29, 2025 (GLOBE NEWSWIRE) -- KALA BIO, Inc. (NASDAQ:KALA), a clinical-stage biopharmaceutical company dedicated to the research, development and commercialization of innovative therapies for rare and severe diseases of the eye, today announced that its CHASE (**C**orneal **H**ealing **A**fter **SE**cretome therapy) Phase 2b clinical trial of KPI-012 for the treatment of persistent corneal epithelial defect (PCED) did not meet the primary endpoint of complete healing of PCED as measured by corneal fluorescein staining. The CHASE trial also failed to achieve statistical significance for key secondary efficacy endpoints and did not show any meaningful difference between either KPI-012 treatment arm and the placebo arm.

Based on the CHASE trial results, KALA plans to cease development of KPI-012 and its mesenchymal stem cell secretome (MSC-S) platform. KALA plans to evaluate its strategic options and as part of its evaluation to engage in discussions with its secured lender. In the interim, the company plans to take steps to preserve cash, including by conducting a reduction in workforce and other cost-saving measures.

“We are disappointed to see the results of the CHASE study given the positive results KPI-012 yielded in the Phase 1b study. KPI-012 continued to be well-tolerated and demonstrated a favorable safety profile but did not demonstrate the efficacy results that would warrant advancing the program for treatment of front-of-the-eye diseases,” said Kim Brazzell, Ph.D., Head of R&D and Chief Medical Officer of Kala BIO. “We would like to thank all of the patients and investigators who participated in in the CHASE trial.”

About CHASE (**C**orneal **H**ealing **A**fter **SE**cretome therapy) **Phase 2b Trial**

The CHASE Phase 2b trial is a multicenter, randomized, double-masked, vehicle-controlled, parallel-group study to evaluate the safety and efficacy of two doses of KPI-012 ophthalmic solution (3 U/mL and 1 U/mL) versus vehicle dosed topically QID for 56 days. The CHASE trial randomized 79 patients across 37 sites in the United States and Latin America with verified PCEDs at baseline that will be eligible for inclusion in the primary efficacy analysis. The primary endpoint is complete healing of PCED as measured by corneal fluorescein staining photographs analyzed by a masked central reading center.

About KALA BIO, Inc.

KALA is a clinical-stage biopharmaceutical company dedicated to the research, development and commercialization of innovative therapies for rare and severe diseases of the eye. KALA’s biologics-based investigational therapies utilize KALA’s proprietary mesenchymal stem cell secretome (MSC-S) platform. KALA’s lead product candidate, KPI-012, is a human MSC-S, which contains numerous human-derived biofactors, such as growth factors, protease inhibitors, matrix proteins and neurotrophic factors. KPI-012 received Orphan Drug and Fast Track designations from the U.S. Food and Drug Administration for the treatment of persistent corneal epithelial defect (PCED), a rare disease of impaired corneal healing.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. Any statements in this press release about KALA’s future expectations, plans and prospects, including but not limited to statements about KALA’s plans to evaluate its strategic options, engage in discussions with its secured lender, preserve cash, conduct a reduction in workforce and other cost-saving measures and other statements containing the words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “likely,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would,” and similar expressions constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: uncertainty regarding what, if any, actions KALA’s secured lender may take to recover amounts owed by KALA; KALA’s ability to successfully identify and pursue strategic options on attractive terms, or at all; uncertainty as to whether the reduction in workforce and other cost-saving measures will result in the anticipated savings and be completed when anticipated; and other important factors, any of which could cause KALA’s actual results to differ from those contained in the forward-looking statements, discussed in the “Risk Factors” section of KALA’s Annual Report on Form 10-K, most recent Quarterly Report on Form 10-Q and other filings KALA makes with the Securities and Exchange Commission. These forward-looking statements represent KALA’s views as of the date of this press release and should not be relied upon as representing KALA’s views as of any date subsequent to the date hereof. KALA does not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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