Kala Pharmaceuticals Announces Positive Safety Update from Cohort 1 of CHASE Phase 2b Clinical Trial Evaluating KPI-012 in Patients with PCED

March 27, 2023

--No safety issues identified in Cohort 1 --
-- Now proceeding to Cohort 2 to evaluate the safety and efficacy of two doses of KPI-012 in a multicenter, randomized, double-masked, vehicle-controlled trial --
-- Topline data for Cohort 2 targeted for 1Q 2024; if positive, trial could potentially serve as first of two pivotal trials required to support submission of a BLA --

ARLINGTON, Mass., March 27, 2023 (GLOBE NEWSWIRE) -- Kala Pharmaceuticals, 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 positive safety data from the first cohort of the CHASE (**C**orneal **H**ealing **A**fter **SE**cretome therapy) Phase 2b clinical trial evaluating KPI-012, a human mesenchymal stem cell secretome (MCS-S), for the treatment of persistent corneal epithelial defect (PCED). The first cohort enrolled two patients, treated with a high dose of KPI-012 (3 U/mL) four times per day (QID). Both patients successfully completed at least one week of dosing with no safety issues observed. The trial will now advance to Cohort 2.

The CHASE trial includes two patient cohorts. The first cohort is an open-label study to evaluate the safety of the high dose of KPI-012 (3 U/mL) dosed topically QID in two patients. The second cohort is a multicenter, randomized, double-masked, vehicle-controlled, parallel-group study to evaluate the safety and tolerability of two doses of KPI-012 ophthalmic solution (3 U/mL and 1 U/mL) versus vehicle dosed topically QID for 56 days in approximately 90 patients. The primary endpoint of the trial is the complete healing of the PCED as measured by corneal fluorescein staining. Kala is targeting reporting topline safety and efficacy data in the first quarter of 2024. If the results are positive, and subject to discussion with regulatory authorities, Kala believes this trial could serve as the first of two pivotal trials required to support the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration.

“We are encouraged by the early safety data from the CHASE Phase 2b trial. Generating positive safety data at the high dose and moving to Cohort 2 represents a significant milestone for our KPI-012 development program. Based on these results, we are moving quickly to initiate the second patient cohort,” said Kim Brazzell, Ph.D., Head of R&D and Chief Medical Officer of Kala Pharmaceuticals. “We believe the multifactorial mechanism of action of KPI-012 can address impaired corneal healing at multiple points in the healing process, potentially enabling us to provide the first therapy to address all underlying etiologies of PCED. We believe KPI-012 could fill a large unmet need in this rare disease and look forward to the continued development of KPI-012 for the estimated 100,000 people annually suffering from PCED in the United States and the thousands of other PCED patients around the world.”

About KPI-012 for Persistent Corneal Epithelial Defect (PCED)

Persistent corneal epithelial defect, which is defined as a persistent non-healing corneal defect or wound that is refractory to conventional treatments, is a rare disease with an estimated incidence in the United States of 100,000 cases per year and 238,000 cases per year in the United States, European Union and Japan combined. PCED can have various etiologies, including neurotrophic keratitis, surgical epithelial debridement, microbial/viral keratitis, corneal transplant, limbal stem cell deficiency and mechanical and chemical trauma and, if left untreated, can lead to infection, corneal ulceration or perforation, scarring, opacification and significant vision loss.

Based on its multifactorial mechanism of action and preclinical and clinical data generated to-date, Kala believes KPI-012 may represent a significant advancement in the treatment of PCED and could become the first approved treatment for PCED across all its various etiologies.

About Kala Pharmaceuticals, 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 that can potentially correct the impaired corneal healing that is an underlying etiology of multiple severe ocular diseases. KPI-012 is currently in clinical development for the treatment of persistent corneal epithelial defect (PCED), a rare disease of impaired corneal healing, for which it has received orphan drug designation from the U.S. Food and Drug Administration. Kala is also targeting the potential development of KPI-012 for the treatment of Limbal Stem Cell Deficiency and ocular manifestations of moderate-to-severe Sjögren's and has initiated preclinical studies to evaluate the potential utility of its MSC-S platform for inherited retinal degenerative diseases, such as Retinitis Pigmentosa and Stargardt Disease. For more information on Kala, please visit www.kalarx.com.

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 expectations with respect to potential advantages of KPI-012 and its MSC-S platform; anticipated timelines to report topline data for the CHASE Phase 2b clinical trial of KPI-012; the potential regulatory pathway for KPI-012; the design of the CHASE Phase 2b clinical trial; the clinical utility of KPI-012 for PCED; plans to pursue research and development of KPI-012 and its MSC-S platform for other indications and other statements containing the words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “likely,” “will,” “would,” “could,” “should,” “continue,” 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: uncertainties inherent in the initiation and

conduct of preclinical studies and clinical trials; uncertainties regarding availability and timing of data from clinical trials; whether results of early clinical trials or trials in different disease indications will be indicative of the results of ongoing or future trials; whether results of the Phase 1b clinical trial of KPI-012 will be indicative of results for any future clinical trials and studies of KPI-012, including the CHASE Phase 2b clinical trial; whether interim data from a clinical trial will be predictive of the results of the trial; uncertainties associated with regulatory review of clinical trials and applications for marketing approvals; Kala's ability to retain and hire key personnel; the impact of extraordinary external events, such as the current pandemic health event resulting from the coronavirus (COVID-19), and their collateral consequences; the sufficiency of cash resources and need for additional financing 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 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.

Investor Contact:

Hannah Deresiewicz
hannah.deresiewicz@sternir.com
212-362-1200