Kala Pharmaceuticals Announces FDA Acceptance of IND Application for KPI-012 for the Treatment of PCED

December 27, 2022

-- On-track to initiate Phase 2b trial in 1Q 2023; Topline data expected in 1Q 2024 --
-- Received remaining $25 million investment under previously announced private placement financing --

ARLINGTON, Mass., Dec. 27, 2022 (GLOBE NEWSWIRE) -- Kala Pharmaceuticals, Inc. (NASDAQ:KALA), a clinical-stage biopharmaceutical company dedicated to the research, development and commercialization of innovative therapies for rare diseases of the eye, today announced that the U.S. Food and Drug Administration (FDA) has accepted an investigational new drug (IND) application for the company's lead product candidate, KPI-012, a human mesenchymal stem cell secretome (MSC-S), initially in development for the treatment of persistent corneal epithelial defect (PCED).

"The acceptance of the KPI-012 IND is an important milestone for Kala, as we work to translate the promise of our MSC-S platform into better outcomes for people living with rare ocular surface diseases," said Kim Brazzell, Ph.D., Head of R&D and Chief Medical Officer of Kala Pharmaceuticals. "We are now turning our focus to clinical execution. We are working closely with investigators to initiate our Phase 2b clinical trial of KPI-012 for PCED in the first quarter of 2023."

The Phase 2b clinical trial will be a multicenter, randomized, double-masked, vehicle-controlled, parallel-group study to evaluate the safety and efficacy of two doses of KPI-012 ophthalmic solution compared to vehicle when dosed topically four times per day (QID) for 56 days. The trial is expected to enroll approximately 90 adult patients with PCED, and the primary endpoint of the trial will be complete healing of the PCED as measured by corneal fluorescein staining. Kala expects to initiate enrollment in the trial in the first quarter of 2023 and expects to report topline data in the first quarter of 2024. If the results are positive, 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 FDA.

In addition, following the FDA's acceptance of the IND application for KPI-012 and under the terms of the private placement announced on November 28, 2022, Kala today sold an aggregate of 43,478 shares of Series E Convertible Non-Redeemable Preferred Stock at a price of $575.00 per share to a life sciences focused-investor for gross proceeds of $25.0 million. In total, Kala raised aggregate gross proceeds of $31.0 million in the private placement.

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. 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 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 Partial Limbal Stem Cell Deficiency and ocular manifestations of moderate-to-severe Sjögren's and plans to initiate preclinical studies to evaluate the potential utility of its MSC-S platform for retinal degenerative diseases. 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 initiate the Phase 2b clinical trial of KPI-012 and report topline data; the design of the 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: Kala's ability to comply with the covenants under its outstanding loan agreement; 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 planned Phase 2b clinical 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 novel 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 the 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 recently filed 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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