Kala Pharmaceuticals Announces Up to $31 Million Private Placement Financing

November 28, 2022

ARLINGTON, Mass., Nov. 28, 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 it has entered into a definitive agreement with a life sciences-focused investor for the sale, in a private placement priced at-the-market under Nasdaq rules, of shares of its common stock and Series E Convertible Non-Redeemable Preferred Stock (Series E Preferred) in two tranches for gross proceeds of up to $31 million.

Under the terms of the agreement, Kala has agreed to sell in a first tranche an aggregate of 76,813 shares of its common stock at a price of $5.75 per share and an aggregate of 9,666 shares of its Series E Preferred at a price of $575.00 per share, for gross proceeds of approximately $6 million. The first tranche is expected to close on or about December 1, 2022. In addition, subject to acceptance by the U.S. Food and Drug Administration (FDA) of Kala's investigational new drug (IND) application for KPI-012 in persistent corneal epithelial defect (PCED), the investor has agreed to purchase in a second tranche an aggregate of 43,478 shares of Series E Preferred at a price of $575.00 per share, for gross proceeds of approximately $25 million.

Kala intends to use proceeds from the financing to advance the clinical development of KPI-012 for the treatment of PCED, as well as for general corporate purposes.

The securities to be sold in the private placement have not been registered under the Securities Act of 1933, as amended, or applicable state securities laws, and may not be offered or sold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of securities of Kala in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or jurisdiction.

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. Kala intends to initiate a Phase 2b clinical trial evaluating the efficacy and safety of two doses of KPI-012 in PCED patients with a broad range of underlying etiologies in the fourth quarter of 2022. If positive, this trial could serve as the first of two pivotal trials needed to support the submission of a Biologics License Agreement (BLA) to the U.S. Food and Drug Administration.

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.

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 the expected closings for the private placement, the anticipated use of proceeds from the private placement 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: whether the conditions for the closing of each tranche of the private placement will be satisfied; Kala's ability to maintain its listing on the Nasdaq Global Select Market; Kala's ability to comply with the covenants under its outstanding loan agreement; the 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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