Kala Pharmaceuticals Announces Submission of Investigational New Drug Application for KPI-012 for the Treatment of Persistent Corneal Epithelial Defect

November 28, 2022

-- On-track to initiate Phase 2b trial in 4Q 2022, with topline data expected in 1Q 2024 --
-- Cash runway extended into 1Q 2025, pending receipt of second tranche from previously announced financing, due upon FDA acceptance of KPI-012 IND --

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 the submission of an investigational new drug (IND) application to the U.S. Food and Drug Administration (FDA) for KPI-012 for the treatment of Persistent Corneal Epithelial Defect (PCED). Subject to acceptance of the IND by the FDA, Kala remains on-track to initiate a Phase 2b clinical trial of KPI-012 for PCED in the fourth quarter of 2022. Topline safety and efficacy data from the trial is expected in the first quarter of 2024. 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 FDA. Following acceptance of the IND for KPI-012 by the FDA, Kala will receive the second tranche from the private placement of securities announced earlier today which, together with current cash on hand, Kala expects will extend its projected cash runway into the first quarter of 2025.

“We are pleased to announce the submission of the IND for PCED, which brings us an important step closer to our goal of delivering the promise of mesenchymal stem cell secretome (MSC-S)-based therapies to address severe ocular diseases,” said Mark Iwicki, Chief Executive Officer and Chairman of Kala Pharmaceuticals. “This accomplishment is well timed with the investment commitment announced earlier today from a life sciences-focused investor, which reflects a belief in the power of our MSC-S platform to address significant unmet needs across a range of rare ophthalmic diseases and, in particular, the potential for KPI-012 to become the first approved prescription therapy indicated for PCED patients with a broad range of underlying etiologies. We look forward to initiating this trial before year end.”

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. 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; the future development or commercialization of KPI-012; regulatory review of its IND submission; plans to initiate and timelines of clinical trials; 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; expectations with respect to the expected closings of each tranche of the private placement announced today and the sufficiency of Kala’s existing cash resources for the period anticipated 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 announced today 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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