Kala Pharmaceuticals Appoints Dr. Francis Mah as Chief Medical Advisor

March 29, 2023

ARLINGTON, Mass., March 29, 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 the appointment of Francis Mah, M.D., as Chief Medical Advisor. In this newly established role, Dr. Mah will provide support for Kala's clinical development and medical activities and will play a key role in interactions with eye care professionals. Dr. Mah will serve in this role on a part time basis while continuing his ongoing position as Director of Cornea and External Disease and the Co-Director, Refractive Surgery at Scripps Clinic.

"We are thrilled to welcome Francis to Kala as our Chief Medical Advisor. His deep expertise in corneal disease, along with his strong background in research and his experience serving as principal investigator on a number of clinical trials, will be extremely valuable in helping us advance the development of KPI-012 for persistent corneal epithelial defect (PCED) and other rare diseases," said Kim Brazzell, Head of R&D and Chief Medical Officer of Kala Pharmaceuticals. "Earlier this week we were excited to announce positive safety data from the first cohort of our CHASE (**C**orneal **H**ealing **A**fter **SE**cretome therapy) Phase 2b clinical trial evaluating KPI-012 for PCED and to share that this trial is advancing to the second and final cohort. With the CHASE trial underway, we look forward to collaborating with Francis to expand our efforts into additional rare diseases of the eye, where KPI-012's multifactorial mechanism of action may prove beneficial."

"I am very excited about Kala's innovative mesenchymal stem cell secretome platform, which I believe can provide a novel solution to improve the care and treatment of multiple rare and severe ocular diseases," said Dr. Mah. "I am particularly excited to partner with the Kala team to advance KPI-012 for the treatment of PCED. As a physician, I am acutely aware of the need for new options, which can safely and effectively facilitate rapid and sustained wound healing, regardless of the underlying disease etiology. I believe KPI-012 has the potential to offer a broad-based treatment option for patients suffering from PCED and look forward to supporting the company in its execution of the CHASE trial, while also exploring opportunities to expand KPI-012 for the treatment of additional rare ocular diseases."

Dr. Mah brings over 20 years of clinical practice as a board-certified ophthalmologist and is an esteemed educator who has disseminated his expertise through more than 80 peer-reviewed papers and various book chapters on his research and has delivered presentations in more than 20 countries on 6 continents. Dr. Mah specializes in advanced corneal, cataract and refractive surgery, and is currently the Director of Cornea and External Disease and the Co-Director, Refractive Surgery at Scripps Clinic Medical Group in La Jolla, CA. He received his B.A. from Dartmouth College, his M.D. from the Medical College of Ohio at Toledo and completed a residency in ophthalmology and a fellowship in cornea and refractive surgery at the University of Pittsburgh.

Dr. Mah has an extensive background in translational research and has been a principal investigator for many clinical trials and investigator-initiated studies. Dr. Mah is past Chair of the Corneal Clinical Committee, current committee member on the FDA Committee, and a member of the Executive Committee of the American Society of Cataract and Refractive Surgery. He is also Co-Chair of the Preferred Practice Patterns for Cornea and External Disease, and member of the cornea section of the Basic and Clinical Science Course for the American Academy of Ophthalmology.

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 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, 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; the clinical utility of KPI-012 for PCED; Kala's 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