Kala Pharmaceuticals Receives FDA Complete Response Letter for KPI-121 0.25% NDA and Plans to Respond with Data From STRIDE 3 Trial

August 8, 2019

-- Targeting Topline Data from STRIDE 3 by the End of 2019 --

WATERTOWN, Mass.--(BUSINESS WIRE)--Aug. 8, 2019-- Kala Pharmaceuticals, Inc. (NASDAQ:KALA), today announced that it received a complete response letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the Company's new drug application (NDA) for KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease. The FDA indicated that efficacy data from an additional clinical trial will be needed to support a resubmission.

Kala continues to enroll patients in its ongoing STRIDE 3 (STRIDE – Short Term Relief In Dry Eye) Phase 3 clinical trial, and expects this trial will serve as the basis of its response to the CRL. Kala is targeting topline data from STRIDE 3 by the end of 2019 and resubmission of the NDA during the first half of 2020. The Company believes this resubmission would be subject to a six-month review under the Prescription Drug User Fee Act. Kala initiated STRIDE 3 in July 2018 at the recommendation of the FDA. The STRIDE 3 trial design reflects specific modifications to the inclusion and exclusion criteria of Kala's previous trials of KPI-121 0.25%, which were implemented to improve the probability of success.

"We remain confident in the potential of KPI-121 0.25% to be the first approved product for the temporary relief of the signs and symptoms of dry eye disease," said Kim Brazzell, Chief Medical Officer of Kala Pharmaceuticals. "We look forward to reporting data from STRIDE 3 and resubmitting the NDA with the goal of obtaining approval and being able to offer KPI-121 0.25% to the millions of patients with dry eye disease."

The STRIDE 3 trial is a multicenter, randomized, double-blind, placebo-controlled, parallel-arm study, comparing KPI-121 0.25% to vehicle (placebo), each dosed four times a day (QID) for two weeks in approximately 900 patients with dry eye disease. Subjects who meet initial screening and inclusion/exclusion criteria undergo a two-week run-in period with vehicle. Subjects who continue to meet inclusion/exclusion criteria after the run-in are randomized to receive either KPI-121 0.25% or vehicle for two weeks.

The NDA for KPI-121 0.25% included data from one Phase 2 and two Phase 3 efficacy and safety trials, STRIDE 1 and STRIDE 2, studying approximately 2,000 patients with dry eye disease.

About KPI-121 0.25%

Kala is developing KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease utilizing a two-week course of therapy. Dry eye disease is a chronic, episodic, multifactorial disease affecting the tears and ocular surface and can involve tear film instability, inflammation, discomfort, visual disturbance and ocular surface damage. KPI-121 0.25% utilizes Kala's AMPPLIFY™ mucus-penetrating particle (MPP) Drug Delivery Technology to enhance penetration of loteprednol etabonate (LE) into target tissue of the eye. Kala has completed one Phase 2 and two Phase 3 clinical trials, STRIDE 1 and STRIDE 2 (STRIDE - Short Term Relief In Dry Eye), of KPI-121 0.25%. A third Phase 3 study, STRIDE 3, is currently ongoing and Kala is targeting topline data by the end of 2019. Kala believes that KPI-121 0.25%'s broad mechanism of action, rapid onset of relief of both signs and symptoms, favorable tolerability and safety profile and the potential to be complementary to existing therapies, could result in a favorable profile for the management of dry eye flares and other dry eye associated conditions.

About Kala Pharmaceuticals, Inc.

Kala is a biopharmaceutical company focused on the development and commercialization of therapeutics using its proprietary AMPPLIFY™ mucus-penetrating particle (MPP) Drug Delivery Technology, with an initial focus on the treatment of eye diseases. Kala has applied the AMPPLIFY Drug Delivery Technology to a corticosteroid, loteprednol etabonate (LE), designed for ocular applications, resulting in the August 2018FDA approval of INVELTYS® for the treatment of inflammation and pain following ocular surgery and its lead product candidate, KPI-121 0.25%, for the temporary relief of the signs and symptoms of dry eye disease.

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, including statements regarding the Company's lead product candidate, KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease, including the Company's belief that changes made to the inclusion/exclusion criteria of STRIDE 3 will improve the probability of success, the Company's belief that resubmission of the NDA would be subject to a six-month review under the Prescription Drug User Fee Act, and the Company targeting to report topline results for STRIDE 3 by the end of 2019 and resubmission of the NDA during the first half of 2020. All statements, other than statements of historical facts, contained in this Press Release, including statements regarding the Company's strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The Company may not actually achieve the plans, intentions or expectations disclosed in its forward-looking statements, and you should not place undue reliance on such forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements as a result of various risks and uncertainties, including but not limited to: whether the Company will be able to successfully implement its commercialization plans for INVELTYS; whether the market opportunity for INVELTYS is consistent with the Company's expectations and market research; uncertainties inherent in the availability and timing of data from ongoing clinical trials, and the results of such trials, including STRIDE 3; whether any additional clinical trials will be initiated or required for KPI-121 0.25% prior to approval of the NDA, or at all, and whether the NDA will be approved; the Company's ability execute on the commercial launch of

INVELTYS on the timeline expected, or at all; whether the Company's cash resources will be sufficient to fund the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements for the Company's expected timeline; other matters that could affect the availability or commercial potential of INVELTYS and the Company's product candidates, including KPI-121 0.25%; and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, discussed in the “Risk Factors” section of the Company’s Annual Report on Form 10-K, most recently filed Quarterly Report on Form 10-Q and other filings the Company makes with the Securities and Exchange Commission. These forward-looking statements represent the Company’s views as of the date of this release and should not be relied upon as representing the Company’s views as of any date subsequent to the date hereof. The Company 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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