Kala Pharmaceuticals Announces Dosing of First Patient in Phase 3 STRIDE 3 Trial of KPI-121 0.25% in Patients with Dry Eye Disease

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WALTHAM, Mass.--(BUSINESS WIRE)--Jul. 31, 2018-- Kala Pharmaceuticals, Inc. (NASDAQ:KALA), a biopharmaceutical company focused on the development and commercialization of therapeutics using its proprietary mucus-penetrating particle (MPP) technology, today announced that the first patient has been dosed in STRIDE 3 (Short Term Relief In Dry Eye), its Phase 3 trial of KPI-121 0.25% for the short-term treatment of dry eye disease.

“We are pleased to initiate the STRIDE 3 trial of KPI-121 0.25%. If approved, KPI-121 0.25% could be the first FDA-approved product for the short-term treatment of dry eye disease,” said Kim Brazzell, Chief Medical Officer. “The STRIDE 3 trial design reflects specific modifications to the inclusion/exclusion criteria of our previous trials to address key factors which we believe will improve the probability of success. We anticipate reporting topline results in the fourth quarter of 2019. We also continue to prepare for the potential approval and launch of INVELTYS™ (KPI-121 1%), which has been granted a target action date under the Prescription Drug User Fee Act (PDUFA) of August 24, 2018, and which, if approved, is expected to be the first twice-daily ocular corticosteroid indicated for the treatment of post-operative ocular inflammation and pain.”

STRIDE 3 Phase 3 Trial Design

The STRIDE 3 trial is a multicenter, randomized, double-blind, placebo controlled, parallel-arm study comparing KPI-121 0.25% to placebo, each dosed four times a day (QID) for 14 days, in approximately 900 patients with dry eye disease. Subjects who meet initial screening and inclusion/exclusion criteria undergo a 2-week run-in period with placebo. Subjects who continue to meet inclusion/exclusion criteria after the run-in are randomized to either KPI-121 0.25% or placebo. The primary endpoint, Day 15 ocular discomfort severity, is based upon a patient diary in which ocular discomfort is recorded daily over the entire course of the trial using a visual analog grading scale. Topline data from this study is expected in the fourth quarter of 2019.

About the KPI-121 0.25% Development Plan

In January 2018, Kala announced topline results for two Phase 3 trials (STRIDE 1 and STRIDE 2), evaluating the safety and efficacy of KPI-121 0.25% versus placebo in patients with dry eye disease. KPI-121 0.25% achieved statistical significance for the primary sign endpoint of conjunctival hyperemia at Day 15 in the intent to treat (ITT) population in both Phase 3 trials. KPI-121 0.25% also achieved statistical significance for the primary symptom endpoint of ocular discomfort severity at Day 15 in the ITT population in STRIDE 1 with a trend towards a treatment effect in STRIDE 2. Statistical significance was achieved in STRIDE 1 for the second primary symptom endpoint of ocular discomfort severity at Day 15 in patients with a more severe baseline discomfort, with a strong trend towards a treatment effect observed for the same endpoint in STRIDE 2. Positive treatment effects were also observed in both trials for the symptom endpoint of ocular discomfort severity in the ITT population at Day 8, which was a key pre-specified secondary endpoint. KPI-121 0.25% was well-tolerated in both Phase 3 trials with elevation in intra-ocular pressure, a known side effect with topical corticosteroids, similar to placebo.

Kala plans to file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) during the second half of 2018. The NDA will include data from three clinical trials studying approximately 2000 patients, including one Phase 2 trial and two Phase 3 efficacy and safety trials. In addition, based upon the recommendation of the FDA, Kala has initiated the STRIDE 3 Phase 3 clinical trial evaluating KPI-121 0.25% for the temporary relief of the signs and symptoms of 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 administered four times a day. 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 mucus-penetrating particle (MPP) technology to enhance penetration of loteprednol etabonate (LE) into target tissue of the eye. In preclinical studies, MPP technology increased delivery of LE into ocular tissues more than three-fold compared to current LE products by facilitating penetration through the tear film mucus. Kala has completed one Phase 2 and two Phase 3 clinical trials of KPI-121 0.25%. 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

Kala is a biopharmaceutical company focused on the development and commercialization of therapeutics using its proprietary mucus-penetrating particle (MPP) technology, with an initial focus on the treatment of eye diseases. Kala has applied the MPP technology to a corticosteroid designed for ocular applications, resulting in two lead product candidates: INVELTYS™ (KPI-121 1%) for the treatment of inflammation and pain following ocular surgery, for which an NDA has been accepted for review by the FDA and given a target action date under the Prescription Drug User Fee Act (PDUFA) of August 24, 2018, and 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 product candidates including INVELTYS (KPI-121 1%) for the treatment of inflammation and pain following ocular surgery and KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease, KPI-121 0.25% potentially being the first FDA-approved product for the short-term treatment of dry eye disease, the anticipated reporting of STRIDE 3

topline results in the fourth quarter of 2019, the Company's plans to file an NDA for KPI-121 0.25% with the FDA during the second half of 2018, and a target action date under the Prescription Drug User Fee Act (PDUFA) of August 24, 2018 for INVELTYS. 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 data from the Company's Phase 3 clinical trials of KPI-121 0.25% will warrant submission and filing of an NDA on the timeline expected, or at all; whether any additional clinical trials will be initiated or required for KPI-121 0.25% prior to submission or filing of an NDA, or at all, and whether any such NDA will be approved; the Company's ability to initiate and complete clinical trials on the timeline expected, or at all; whether the results of clinical trials will be positive and/or replicate the results from earlier clinical development and/or preclinical studies; that post-hoc analyses are normally given less weight by regulatory authorities than pre-specified analyses; whether the Company's NDA for INVELTYS will be approved by its PDUFA date, or at all; uncertainties inherent in the availability and timing of data from ongoing clinical trials; uncertainties related to the Company's ability to obtain regulatory approvals to conduct trials or to market products; the Company's ability to build a sales force and prepare for commercial launch 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 the Company's product candidates; 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 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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