Kala Pharmaceuticals Announces Completion of Enrollment of STRIDE 3 Trial for EYSUVIS™ (KPI-121 0.25%) for Dry Eye Disease

January 15, 2020

–STRIDE 3 Topline Data Targeted in First Quarter of 2020–

WATERTOWN, Mass.--(BUSINESS WIRE)--Jan. 15, 2020-- Kala Pharmaceuticals, Inc. (Kala) (NASDAQ:KALA), a biopharmaceutical company focused on the development and commercialization of therapeutics using its proprietary AMPPLIFY™ mucus-penetrating particle (MPP) Drug Delivery Technology, today announced that it has completed enrollment in its STRIDE 3 (STRIDE – Short Term Relief In Dry Eye) Phase 3 clinical trial for KPI-121 0.25%, its product candidate for the short-term treatment of dry eye disease. If approved, Kala plans to commercialize KPI-121 0.25% under the brand name EYSUVIS™. Kala is targeting to report top-line results from this trial during the first quarter of 2020 and resubmission of the EYSUVIS New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the first half of 2020. Kala believes this resubmission would be subject to a six-month review.

“Today’s announcement represents a significant milestone for Kala,” said Kim Brazzell, Chief Medical Officer of Kala. “If approved, we believe EYSUVIS could become the preferred prescription therapy for dry eye flares, which affect the vast majority of dry eye patients. We thank the many patients who participated in this trial, and we are also grateful to our study sites and investigators.”

The STRIDE 3 trial is a multicenter, randomized, double-masked, placebo-controlled, parallel-arm study, comparing EYSUVIS 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 EYSUVIS or vehicle for two weeks. The STRIDE 3 trial design reflects specific modifications to the inclusion and exclusion criteria of Kala’s previous trials of EYSUVIS, which were implemented to improve the probability of success. Kala expects that data from the STRIDE 3 trial will serve as the basis for the resubmission of the EYSUVIS NDA to the FDA.

About Kala Pharmaceuticals, Inc.

Kala is a biopharmaceutical company focused on the development and commercialization of therapeutics using its proprietary AMPPLIFY™ 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 2018 FDA approval of INVELTYS® (loteprednol etabonate ophthalmic suspension) 1% and its investigational product, EYSUVIS (loteprednol etabonate ophthalmic suspension) 0.25%, which is being studied 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, EYSUVIS, for the short-term treatment 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 targeting topline results for STRIDE 3 in the first quarter of 2020 and resubmission of the EYSUVIS NDA to the FDA in the first half of 2020, and that the NDA resubmission would be subject to a six-month review under PDUFA. 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 and EYSUVIS 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 EYSUVIS 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 EYSUVIS, if and when approved, on the timeline expected, or at all; whether the Company will be able to generate its projected net product revenue 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 EYSUVIS; 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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