Kala Pharmaceuticals Announces Statistically Significant Results for Primary and Key Secondary Endpoints in STRIDE 3 Clinical Trial Evaluating EYSUVIS™ for Signs and Symptoms of Dry Eye Disease

March 9, 2020

– STRIDE 3 Met Both Prespecified Primary Efficacy Endpoints, Ocular Discomfort Severity in the Overall ITT Population and in ITT Patients with More Severe Baseline Discomfort –
– STRIDE 3 Met Key Sign Endpoint of Conjunctival Hyperemia –
– Data Enables EYSUVIS NDA Resubmission in 2Q 2020 –
– Potential Approval and Launch by Year-End 2020 –
– Conference Call and Webcast Today at 8:00 a.m. ET –

WATERTOWN, Mass.--(BUSINESS WIRE)-- Kala Pharmaceuticals, Inc. (Kala) (NASDAQ:KALA), a biopharmaceutical company focused on the discovery, development and commercialization of innovative therapies for diseases of the eye, today announced positive topline results from STRIDE 3, a Phase 3 clinical trial evaluating KPI-121 0.25%, which Kala plans to commercialize under the brand name EYSUVIS (loteprednol etabonate ophthalmic suspension) 0.25%, for the treatment of dry eye disease. STRIDE 3 met both of its primary efficacy endpoints, demonstrating a statistically significant improvement in the symptom endpoint of ocular discomfort severity (ODS) at day 15 in the overall intent-to-treat (ITT) population (p=0.0002) and in the predefined subgroup of ITT patients with more severe ocular discomfort at baseline (p=0.0007). Statistical significance was also achieved in the key secondary endpoints of conjunctival hyperemia at day 15 in the ITT population (p<0.0001) and ODS at day 8 in the ITT population (p=0.0282). Significant results were also observed for total corneal staining at day 15 in the ITT population (p=0.0042). EYSUVIS was well tolerated, with adverse events and intraocular pressure increases comparable to vehicle. Kala plans to utilize these data as the basis for a Class 2 resubmission of the New Drug Application (NDA) for EYSUVIS in the second quarter of 2020, with an expected six-month review timeline by the U.S. Food and Drug Administration (FDA).

“These data reinforce the potential of EYSUVIS to transform the treatment landscape for dry eye disease,” said Dr. Edward Holland, Director of Cornea Services at Cincinnati Eye Institute and Professor of Ophthalmology at the University of Cincinnati. “EYSUVIS would be the first prescription dry eye product developed specifically to address the acute treatment needs of patients with dry eye disease, including dry eye flares that are experienced by the vast majority of patients. If approved, I believe EYSUVIS would become a first-line therapy for patients at all stages of dry eye disease.”

“I’m pleased to hear the exciting news that EYSUVIS has successfully achieved the primary and key secondary endpoints in the STRIDE 3 clinical trial,” said Dr. Kelly Nichols, Dean of the University of Alabama at Birmingham School of Optometry. “If approved, EYSUVIS will address an important unmet need for dry eye patients. Most dry eye patients do not experience continual symptoms. I believe these patients will benefit greatly from an effective and well-tolerated short-term treatment that can be taken when they experience flares.”

“We are thrilled with the results of STRIDE 3, which build on our prior clinical experience with EYSUVIS in our Phase 2, STRIDE 1 and STRIDE 2 trials,” said Mark Iwicki, Chairman, President and Chief Executive Officer of Kala Pharmaceuticals. “We would like to express our sincere appreciation to the investigators and nearly 3,000 patients who participated in the trials. We are now focusing on finalizing the NDA resubmission, which is targeted for the second quarter of 2020, and on preparing for a potential U.S. approval and launch by the end of the year. We look forward to delivering this important new medicine to patients.”

If approved, Kala intends to commercialize EYSUVIS in the United States with its specialty sales force, which it plans to increase to a total of approximately 100 to 125 sales representatives, who will promote both EYSUVIS and INVELTYS® (loteprednol etabonate ophthalmic suspension) 1%.

STRIDE 3 Topline Results:

STRIDE 3 was 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 901 patients with dry eye disease. The ITT population consisted of 447 patients in the EYSUVIS treatment group and 454 patients receiving vehicle. Patients who met initial screening and inclusion/exclusion criteria then underwent a two-week run-in period with vehicle. Patients who continued to meet inclusion/exclusion criteria after the run-in were then randomized to receive either EYSUVIS or vehicle for two weeks. ODS was graded daily by the patient over the entire course of the trial using a visual analog grading scale (measured on a scale ranging from 0 to 100 mm) recorded in a patient diary.

STRIDE 3 achieved both of its independent primary endpoints, demonstrating a statistically significant reduction in the symptom endpoint of ODS from baseline to day 15 compared to vehicle control in both the overall ITT population (p=0.0002) and in a pre-defined subgroup of ITT patients with more severe baseline ocular discomfort (p=0.0007), defined as patients who scored greater than or equal to 68 mm in baseline ocular discomfort. These data replicate the achievement of both primary symptom endpoints of STRIDE 1 (p<0.0001 in the overall ITT population and p=0.0008 in the pre-defined ITT subgroup with more severe ocular discomfort at baseline). Statistical significance was also achieved in the key secondary endpoint of conjunctival hyperemia at day 15 in the ITT population (p<0.0001). This result replicates the achievement of the results of STRIDE 1 and STRIDE 2, where statistical significance was demonstrated for conjunctival hyperemia at day 15 in the ITT population as a prespecified primary endpoint in each of those trials. Statistical significance was also achieved for the key secondary endpoint of ODS at day 8 in the ITT population (p=0.0282), which was consistent with STRIDE 1 (p=0.0011) and STRIDE 2 (p=0.0408). Significant improvement was also observed for corneal staining in the ITT population (p=0.0042), consistent with the result in STRIDE 2 (p=0.0314).

EYSUVIS was well-tolerated in this trial, consistent with prior clinical trials. The most common adverse event observed in STRIDE 3 was instillation site pain, which was reported by 2.9% in the EYSUVIS group compared to 1.5% in the vehicle group. Elevations in intraocular pressure (IOP), a known side effect with topical corticosteroid administration, were similar between the two groups, with no patients in either the EYSUVIS or vehicle group experiencing an increase in IOP of 5 mmHg or greater that resulted in an IOP of greater than 21 mmHg in the study eye.

Conference Call Information:

Kala will host a live conference call and webcast today, March 9, 2020 at 8:00 a.m. ET to review the STRIDE 3 data and discuss next steps for the EYSUVIS program. To access the conference call, please dial 866-300-4091 (domestic callers) or 703-736-7433 (international callers) five minutes prior to the start of the call and provide the conference ID: 4458057. To access the slides that will be presented during the conference call, and to access a subsequent archived recording of the call, please visit the “Investors & Media” section on the Kala website at http://kalarx.com.

About EYSUVIS:

Kala is developing EYSUVIS (loteprednol etabonate ophthalmic suspension) 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. EYSUVIS 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 three Phase 3 clinical trials, STRIDE 1, STRIDE 2 and STRIDE 3 (STRIDE - Short Term Relief In Dry Eye) for EYSUVIS. Kala believes that EYSUVIS' 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 preferred 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 discovery, development and commercialization of innovative therapies for diseases of the eye. Kala has applied its AMPPLIFY™ mucus penetrating particle Drug Delivery Technology to a corticosteroid, loteprednol etabonate (LE), designed for ocular applications, resulting in the January 2019 launch of INVELTYS® (loteprednol etabonate ophthalmic suspension) 1% and its investigational product candidate, 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 INVELTYS and the Company's lead product candidate, EYSUVIS, for the temporary relief of the signs and symptoms of dry eye disease, including the Company targeting resubmission of its NDA to the FDA in the second quarter of 2020, expectations regarding timing of FDA review of the NDA and potential launch by year-end 2020, the market potential for EYSUVIS and the Company’s plans to expand its commercial sales force. 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 EYSUVIS, if approved; whether the market opportunity for INVELTYS and EYSUVIS is consistent with the Company’s expectations and market research; 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 for EYSUVIS 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 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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