Kala Pharmaceuticals Announces Topline Results for Two Phase 3 Trials (STRIDE 1 and STRIDE 2) of KPI-121 0.25% in Dry Eye Disease

January 5, 2018

- *Statistical significance achieved for the primary sign endpoint, conjunctival hyperemia at Day 15 in the ITT population, in STRIDE 1 (p<0.0001)*
- *Statistical significance achieved for the primary sign endpoint, conjunctival hyperemia at Day 15 in the ITT population, in STRIDE 2 (p<0.0001)*
- *Statistical significance achieved for the primary symptom endpoint, ocular discomfort severity at Day 15 in the ITT population, in STRIDE 1 (p<0.0001)*
- *Ocular discomfort severity at Day 15 in the ITT population showed improvement but did not reach statistical significance in STRIDE 2 (p=0.1298)*
- *Statistical significance for ocular discomfort severity at Day 15 in patients with more severe baseline discomfort was achieved in STRIDE 1 (p=0.0008), with a trend towards a treatment effect (p=0.0799) in STRIDE 2*
- *Positive treatment effects observed for ocular discomfort severity in the ITT population at Day 8, a key secondary endpoint in both STRIDE 1 (p=0.0011) and STRIDE 2 (p=0.0408)*
- *KPI-121 0.25% was well-tolerated with elevations in IOP similar to placebo*
- *Conference call today at 8:00 AM Eastern Time*

WALTHAM, Mass.--(BUSINESS WIRE)--Jan. 5, 2018-- Kala Pharmaceuticals, Inc. (NASDAQ:KALA), today announced topline results from its two Phase 3 clinical trials, STRIDE 1 and STRIDE 2 (STRIDE - **S**hort **T**erm **R**elief **I**n **D**ry **E**ye), evaluating the safety and efficacy of KPI-121 0.25% versus placebo in patients with dry eye disease.

In the STRIDE 1 trial, statistical significance was achieved for the primary sign endpoint of conjunctival hyperemia change from baseline to day 15 in the ITT population (p<0.0001) and the primary symptom endpoint of ocular discomfort severity change from baseline to day 15 in the ITT population (p<0.0001). Statistical significance was also achieved for a second pre-specified primary symptom endpoint of ocular discomfort severity change from baseline to day 15 in patients with more severe baseline ocular discomfort (p=0.0008). Statistical significance was not achieved for a second pre-specified primary sign endpoint, inferior corneal staining change from baseline to day 15 (p=0.1128). A positive treatment effect for ocular discomfort was also observed in the ITT population at day 8 (p=0.0011).

KPI-121 was well tolerated in this trial with the most common adverse event in STRIDE 1 being instillation site pain, which was observed in 6.1% of patients in both the KPI-121 treatment group and the placebo group. The only other adverse event reported by greater than 1% of patients was eye irritation, which was reported in 1.1% of patients on KPI-121 vs. 1.5% of patients on placebo. Elevations in IOP, a known side effect with topical corticosteroid administration, were similar between the two groups with 0.4% in the KPI-121 group experiencing an increase in IOP of 5 mm of mercury (mmHg) or greater resulting in an IOP of 21 mmHg or greater compared to 0.4% in the placebo group.

In the STRIDE 2 trial, statistical significance was achieved for the primary sign endpoint of conjunctival hyperemia change from baseline to day 15 in the ITT population (p<0.0001). Statistical significance was not achieved for the primary symptom endpoint of ocular discomfort severity change from baseline to day 15 in the ITT population (p=0.1298), although a positive treatment effect was observed at day 8 (p=0.0408), a key secondary endpoint. A trend towards a positive treatment effect was observed for ocular discomfort severity change from baseline to day 15 in the patients with more severe baseline ocular discomfort (p=0.0799), which was a key secondary endpoint in this trial. KPI-121 was well tolerated in this trial with instillation pain being the most common adverse event In STRIDE 2 as reported by 5.7% of patients in the KPI-121 treatment group vs. 4.4% in the placebo group. The only other adverse event reported by greater than 1% of patients was blurred vision, which was reported in 0.2% of patients on KPI-121 vs. 1.3% of patients on placebo. Elevations in IOP were similar between the two groups with 1.1% in the KPI-121 group experiencing an increase in IOP of 5 mmHg or greater resulting in an IOP of 21 mmHg or greater compared to none in the placebo group.

“We are pleased with the positive topline results of STRIDE 1, in which KPI-121 demonstrated statistically significant improvements in primary sign and symptom endpoints and are encouraged with the results in STRIDE 2, which showed statistical significance for the primary sign endpoint. Although we did not achieve statistical significance for the primary symptom endpoint in STRIDE 2, we did observe a strong trend towards a positive treatment effect in symptoms in more symptomatic patients, for which we achieved statistical significance in STRIDE 1,” said Mark Iwicki, Chief Executive Officer of Kala Pharmaceuticals. “We will continue to analyze the results of both Phase 3 trials and the totality of the data from all 3 trials conducted to date and expect to discuss our clinical program with the FDA. We believe that our preliminary, unaudited December 31, 2017 cash balance of approximately $114 million puts us in a strong position as we maintain our focus on moving this program forward to serve patients with dry eye disease.”

The two Phase 3 clinical trials were each multicenter, randomized, double-masked, placebo controlled, parallel-arm studies comparing KPI-121 to placebo each dosed four times a day (QID) for 14 days. Subjects who met initial screening and inclusion/exclusion criteria underwent a 2-week run-in period with placebo dosed in each eye QID for 14 days. Subjects who continued to meet inclusion and exclusion criteria after the run-in were randomized to either KPI-121 or placebo. A total of 918 patients were randomized in STRIDE 1 and 909 patients were randomized in STRIDE 2. Ocular discomfort severity was graded daily by the patient over the entire course of the trial using a visual analog grading scale recorded in a patient diary.

Conference Call

Kala will hold a conference call on Friday, January 5, 2018 at 8:00 AM ET to discuss results of the two Phase 3 pivotal trials of KPI-121 0.25% in dry eye disease. The dial-in numbers are 1-866-300-4091 for domestic callers and 1-703-736-7433 for international callers. The conference ID is 5364789. For an archived recording of the call and question and answer session, please visit the “Investors & Media” section on the Kala website at http://kalarx.com/.

Presentation at the 36th Annual J.P. Morgan Healthcare Conference

Mark Iwicki, Chairman and Chief Executive Officer of Kala, will provide a corporate update on Monday, January 8, 2018 at 11:30 AM PT, followed by a question and answer session at 12:00 PM PT at the 36th Annual J.P. Morgan Healthcare Conference held at the Westin St. Francis Hotel in San Francisco, CA. For a live webcast and subsequent archived recording of the presentation and question and answer session, please visit the “Investors & Media” section on the Kala website at http://kalarx.com/.

About Dry Eye Disease

Dry eye disease is a chronic, episodic, multifactorial disease affecting the tears and ocular surface that can result in tear film instability, inflammation, discomfort, visual disturbance and ocular surface damage. Dry eye disease is estimated to affect approximately 33 million people in the United States, based on an estimated prevalence of 14.5% as described in The Beaver Dam Offspring Study, a major epidemiological study published in 2014 in the American Journal of Ophthalmology. Dry eye disease can have a significant impact on quality of life and can potentially cause long-term damage to the ocular surface. In addition, the vast majority of dry eye patients experience acute exacerbations of their symptoms, which are commonly referred to as flares, at various times throughout the year. These flares can be triggered by numerous factors which cause ocular surface inflammation and impact tear production and/or tear film stability.

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 that can involve tear film instability, inflammation, discomfort, visual disturbance and ocular surface damage. KPI-121 0.25% utilizes Kala’s 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 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 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 that would benefit from temporary relief of dry eye signs and symptoms.

About Kala Pharmaceuticals, Inc.

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. The product candidates are INVELTYS™ (KPI-121 1%) for the treatment of inflammation and pain following ocular surgery, for which we have submitted a NDA, 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 development and regulatory status of 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. 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 our Phase 3 clinical trials of KPI-121 0.25% will warrant submission of an NDA on the timeline expected, or at all, whether any additional clinical trials will be required prior to submission of an NDA and whether any such NDA will be approved; that topline data is based on preliminary analysis of key efficacy and safety data, and such data could change following a more comprehensive review and may not accurately reflect the complete results of our clinical trials; whether our 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; expectations for regulatory approvals to conduct trials or to market products; whether the Company’s cash resources will be sufficient to fund the Company’s foreseeable and unforeseeable operating expenses and capital expenditure requirements; the risk that our audited financial results for the year ended December 31, 2017, including cash on hand, may differ materially from our estimated results for these periods as a result of the completion of year-end closing procedures, 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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