

Kala Pharmaceuticals Announces Positive Results from Confirmatory Phase 3 Trial of KPI-121 1% Following Cataract Surgery

- KPI-121 1% ophthalmic suspension demonstrated effective resolution of ocular inflammation and pain following cataract surgery when dosed twice-a-day for two weeks -

- Kala's two ongoing Phase 3 trials in dry eye disease expected to complete in late 2017 -

WALTHAM, Mass., May 1, 2017 -- Kala Pharmaceuticals, Inc. (Kala), a developer of innovative ophthalmic medicines based on its proprietary mucus-penetrating particle (MPP) technology, today announced positive top-line results from its confirmatory Phase 3 trial of KPI-121 1% for the treatment of inflammation and pain in patients who have undergone cataract surgery. KPI-121 1% dosed twice-a-day for two weeks achieved statistical significance versus placebo for both primary efficacy endpoints and all secondary endpoints. KPI-121 1% was well tolerated with no significant treatment-related safety findings observed during the trial. These positive trial results are a follow on to Kala's first Phase 3 trial for KPI-121 1% following cataract surgery that also achieved statistical significance for both primary endpoints with twice-a-day dosing.

"The significant improvement in the treatment of inflammation and pain with twice-a-day dosing of KPI-121 in this trial builds on the success of our first Phase 3 trial in cataract surgery," said Kim Brazzell, Ph.D., Chief Medical Officer of Kala. "We believe KPI-121 represents an important, near-term product opportunity for Kala as the first twice-a-day dosed steroid product for patients with post-operative inflammation and pain following ocular surgery. Based on the success of this trial, our plan is to submit a New Drug Application to the FDA for KPI-121 1% for the treatment of post-operative inflammation and pain following ocular surgery in late 2017."

The Phase 3 multi-center, randomized, double-masked, placebo-controlled, parallel-group trial in 520 patients was designed to evaluate the efficacy and safety of KPI-121 1% ophthalmic suspension dosed twice-a-day, versus placebo, in patients who experienced anterior ocular inflammation following cataract surgery. Patients were randomized to receive either KPI-121 1% or corresponding placebo, and both were administered twice-a-day for two weeks, with evaluations at days four, eight and 15. The primary efficacy endpoints were the proportion of patients with complete resolution of anterior chamber cells (a marker of ocular inflammation) in the study eye at day eight, and the proportion of subjects with Grade 0 pain in the study eye at day eight.

Statistically significant differences favoring KPI-121 1% administered twice-a-day versus placebo were achieved for both primary endpoints, the proportion of patients with complete resolution of anterior chamber cells at day 8 ($p=0.01$) and proportion of patients with complete resolution of ocular pain at day 8 ($p<0.0001$). Statistical significance was also achieved for all predefined secondary endpoints (complete resolution of anterior chamber flare at day 4, complete resolution of pain at day 4, and mean change in anterior chamber cells at day 4). Each case maintained through day 15 with no need for rescue medication.

Dr. Edward Holland, Professor of Ophthalmology, University of Cincinnati and Director, Cornea Service, Cincinnati Eye Institute, commented, "Rapid and effective relief of pain and inflammation is the key goal of the management of patients following ocular surgery. With proven safety and efficacy with a twice-a-day dosing regimen, KPI-121 1% will add an important tool to our post-operative armamentarium as a safe, effective and convenient alternative to currently marketed topical corticosteroids, which are all recommended for dosing four times a day."

About KPI-121

KPI-121 is a novel nanoparticle formulation of loteprednol etabonate utilizing Kala's proprietary mucus-penetrating particle (MPP) technology to enhance penetration into target tissues of the eye. In pre-clinical rabbit studies, MPP has been shown to increase loteprednol etabonate delivery into ocular tissues four-fold by facilitating penetration through the tear film mucus. KPI-121 has been studied in over 1,300 patients for the indications of temporary relief of the signs and symptoms of dry eye disease and the post-operative treatment of inflammation and pain following ocular surgery. Kala is currently conducting two phase 3 trials in dry eye disease with expected completion in 2017.

About Kala Pharmaceuticals, Inc.

Kala is a biopharmaceutical company focused on the development and commercialization of therapeutics, using our proprietary MPP technology, with an initial focus on the treatment of eye diseases. In addition to KPI-121, Kala is evaluating compounds in its topically applied MPP receptor tyrosine kinase inhibitor program. Beyond ophthalmology, Kala's proprietary MPP technology has potential applications in women's reproductive health, respiratory and gastrointestinal diseases, and other indications.

Kala was founded by leaders in the fields of nanomedicine and biopharmaceutical engineering, and is backed by leading life sciences investors including OrbiMed, Longitude, Polaris, RA Capital Management, Vivo Capital, Third Rock Ventures, CAM Capital, Lux Capital, CVF, LLC, and Ysios Capital.

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