Kala Pharmaceuticals Announces Positive Results from Phase 2 Trial of KPI-121 in Dry Eye Disease

- KPI-121 meets primary sign endpoint, demonstrating statistical superiority over vehicle in reducing conjunctival hyperemia -

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WALTHAM, Mass., April 1, 2015 -- Kala Pharmaceuticals, Inc. (Kala), a developer of innovative ophthalmic products based on its proprietary mucus-penetrating particle (MPP) technology, today announced positive top-line results from a Phase 2 clinical trial of KPI-121, its nanoparticle loteprednol etabonate MPP product candidate, in patients with dry eye disease. KPI-121 achieved statistical significance for the primary sign endpoint of bulbar conjunctival hyperemia, and promising trends were observed for key symptom endpoints.

"The achievement of statistical significance for the primary sign endpoint in this relatively small trial is an extremely important accomplishment," said Kim Brazzell, PhD, Chief Medical Officer of Kala. "We believe this to be one of the first times an initial Phase 2 dry eye trial has achieved a primary endpoint. We are also encouraged by the promising trends seen in the trial's symptom endpoints, and we believe these data will inform further clinical development by us for this important disease."

The Phase 2 multi-center, randomized, double-masked, parallel-group trial compared 0.25% KPI-121 to vehicle, each dosed four times a day for 28 days, in 150 patients with dry eye disease. Patients treated with KPI-121 achieved statistical significance for the primary clinical sign endpoint of bulbar conjunctival hyperemia at day 29 of the trial (p=0.0387). Although KPI-121 did not achieve statistical significance for the primary symptom endpoint of ocular discomfort, the trial showed promising trends toward improvement in this and other symptom endpoints, particularly in patients with more severe baseline ocular discomfort. KPI-121 was generally well tolerated, with no significant treatment-related safety findings observed during the course of the trial. The only treatment-emergent adverse event reported in greater than 3% of patients was instillation site pain, which was reported in 6.9% of patients treated with KPI-121 compared to 3.8% of patients treated with vehicle.

About KPI-121

KPI-121 is a novel nanoparticle formulation of loteprednol etabonate utilizing Kala's proprietary MPP technology to enhance penetration into target tissues of the eye. KPI-121 has been

studied in multiple clinical trials, including 1% and 0.25% formulations for the treatment of post-surgical ocular inflammation and pain and a 0.25% formulation for dry eye and meibomian gland disease.

About Kala Pharmaceuticals, Inc.

Kala is a clinical stage pharmaceutical company focused on innovative nanoparticle-based treatments for ocular diseases affecting both front and back of the eye. Kala leverages its proprietary mucus-penetrating particle (MPP) technology to develop topical ophthalmic formulations with enhanced delivery into ocular tissue by facilitating penetration through the tear film mucus. Beyond ophthalmology, Kala's 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 Crown Venture Fund, Lux Capital, Polaris Partners, Third Rock Ventures and Ysios Capital. For more information, please visit Kala's website at www.kalarx.com.

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