

Kala Pharmaceuticals Announces Positive Results from Phase 3 Trial of KPI-121 in Cataract Surgery

- KPI-121 meets all primary endpoints, achieving statistical superiority over vehicle for elimination of inflammation and pain following cataract surgery when dosed either twice or four times daily -

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 3 clinical trial of KPI-121, its nanoparticle loteprednol etabonate MPP product candidate, for the treatment of inflammation and pain in patients who had undergone cataract surgery. KPI-121 achieved all primary efficacy endpoints and was generally well tolerated, with no significant treatment-related safety findings observed during the course of the trial.

“We are very pleased with these results,” said Kim Brazzell, PhD, Chief Medical Officer of Kala. “Not only do the results provide support for a potential near-term product opportunity with possible advantages over current therapies, but we believe the results have also demonstrated that our MPP technology has the potential to enhance ocular drug delivery to allow reduction of both dose and dosing frequency while maintaining safety and clinical benefit.”

The Phase 3 multi-center, randomized, double-masked, vehicle-controlled, parallel-group trial in 380 patients was designed to evaluate two dosing regimens of KPI-121 ophthalmic suspension versus vehicle in patients undergoing cataract surgery. Patients were randomized to receive either 0.25% KPI-121 four times daily, 1.0% KPI-121 two times daily or their corresponding vehicles administered for two weeks.

At day eight, statistically significant differences favoring KPI-121 were achieved for the primary endpoint of complete resolution of inflammation with both 1% KPI-121 dosed twice a day ($p=0.0024$) and 0.25% KPI-121 dosed four times a day ($p < 0.0001$). Complete resolution of ocular pain by day eight (also a primary endpoint) was achieved for 1% KPI-121 dosed twice a day ($p=0.0019$) and 0.25% KPI-121 dosed four times a day ($p=0.0003$).

“Ocular pain and inflammation is a significant issue among patients who have undergone cataract surgery, and rapid and efficient treatment for this inflammation is paramount,” said

Terry Kim, M.D., Professor of Ophthalmology at Duke University. “Kala’s clinical data demonstrating that twice daily dosing of KPI-121 was effective in reducing inflammation and pain within one week of initiation of treatment are very encouraging, as current corticosteroids approved in the United States for this use are indicated for four times a day dosing during the first two weeks of therapy.”

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.

Contact:

Kari Watson

(781) 235-3060

kwatson@macbiocom.com

or Hunter Marshall

(650) 342-1000

hmarshall@macbiocom.com

MacDougall Biomedical Communications