

FOR IMMEDIATE RELEASE

Kala Pharmaceuticals Initiates Phase 2 Clinical Trial to Evaluate LE-MPP (KPI-121) in Patients with Retinal Vein Occlusion and Diabetic Macular Edema

Company Also Advances Additional Phase 2 Trial Leveraging Nanoparticle Platform in Meibomian Gland Disease

Waltham, Mass., July 31, 2014 – [Kala Pharmaceuticals, Inc.](#), a leading developer of innovative nanotechnology-based ophthalmic products leveraging the company’s proprietary Mucus Penetrating Particle (MPP) platform, today announced the initiation of a Phase 2 clinical trial (KPI-121-C-004) to evaluate KP-121, the company’s loteprednol etabonate MPP (“LE-MPP”) drug product, in patients with intraretinal or subretinal fluid secondary to retinal vein occlusion (RVO) or diabetic macular edema (DME). In addition, Kala has initiated a Phase 2 clinical trial (KPI-121-C-003) of LE-MPP in subjects with meibomian gland disease (MGD).

“We are excited about the progress of our lead nanotechnology-based program, LE-MPP, with four active clinical trials,” said Kim Brazzell, Ph.D., Chief Medical Officer of Kala. “With the initiation of our latest trial in RVO and DME, Kala is making significant progress toward demonstrating the unique ability of Kala’s MPP platform to deliver drugs to the back of the eye following topical administration.”

Phase 2 Clinical Trial in RVO and DME (KPI-121-C-004)

In this Phase 2, single-masked randomized trial, Kala will investigate the efficacy and safety of 1% LE-MPP and 0.25% LE-MPP dosed four times daily in patients having measurable intraretinal or subretinal fluid secondary to RVO or DME. Kala aims to enroll up to 20 patients at two centers in the U.S.

This exploratory trial was designed in conjunction with Jeffery S. Heier, M.D., Director of Vitreoretinal Service at Ophthalmic Consultants of Boston, who will serve as one of two lead investigators in the trial, along with David S. Boyer, M.D. of Retina-Vitreous Associates Medical Group in Beverly Hills, California.

“The potential to deliver substantial amounts of drug to tissues in the back of the eye using non-invasive topical administration would represent a significant advance in the treatment of retinal disease,” said Dr. Heier. “Kala has generated promising preclinical data, and we look forward to further evaluating the company’s nanotechnology to determine if it offers potential for a less-invasive treatment for patients.”

Phase 2 Clinical Trial in Meibomian Gland Disease (KPI-121-C-003)

In this Phase 2, double-masked, randomized trial of LE-MPP, Kala will study the safety and efficacy of 0.25% LE-MPP compared to vehicle dosed four times daily in subjects with meibomian gland disease. Kala aims to enroll approximately 150 patients in up to 10 centers in the U.S.

In June 2014, Kala initiated dosing in two other trials to evaluate LE-MPP: a Phase 3 trial (KPI-121-C-001) to evaluate the safety and efficacy of LE-MPP in managing inflammation and pain associated with cataract surgery, and a Phase 2 trial (KPI-121-C-002) to investigate the safety and efficacy of low-dose LE-MPP in patients with dry eye disease. In addition, the company continues to advance its novel, small molecule Receptor Tyrosine Kinase Inhibitor (RTKi)-MPP program towards a development candidate selection.

About Diabetic Macular Edema and Retinal Vein Occlusion

Diabetic macular edema (DME) is the swelling of the retina in diabetes mellitus due to leaking of fluid from blood vessels within the macula, the central portion of the retina. DME is common in patients with diabetes, and can cause blurring of central vision, making it difficult to focus clearly.

Retinal vein occlusion (RVO) is blockage of the small veins that carry blood away from the retina, and is most often caused by hardening of the arteries (atherosclerosis) and the formation of a blood clot. RVO can cause sudden blurring or vision loss in all or part of one eye. It is a sign of a general blood vessel (vascular) disease, and is mostly found in the elderly.

About Meibomian Gland Dysfunction

Meibomian gland disease is a chronic disease characterized by inflammation, hypersecretion or abnormal excreta of the meibomian glands. The resulting decrease in lipids on the tear film causes it to evaporate quicker and often manifests as evaporative dry eye. It is one of the most common disorders encountered with ophthalmologists and impacts the outcome of refractive and other surgeries.

About Kala Pharmaceuticals

Kala Pharmaceuticals, Inc. is advancing innovative nanotechnology-based treatments for ocular diseases with significant unmet needs in both front and back of the eye. Kala leverages the company's proprietary Mucus Penetrating Particle (MPP) platform technology to develop topical ophthalmic formulations with enhanced exposure into ocular tissue by facilitating penetration through the mucus layer of the tear film. Beyond ophthalmology, Kala's MPP technology has potential applications in other indications, such as respiratory, women's reproductive health and gastrointestinal diseases.

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 www.kalarx.com.

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