

FOR IMMEDIATE RELEASE

Kala Pharmaceuticals Initiates Phase 3 Clinical Trial for Treatment of Post-Surgical Ocular Inflammation and Phase 2 Clinical Trial in Dry Eye Disease

Advances Two U.S. Clinical Trials for Lead Ophthalmic Products Utilizing Proprietary Mucus Penetrating Particle Platform

Waltham, Mass., June 19, 2014 – [Kala Pharmaceuticals, Inc.](#), a leading developer of innovative ophthalmic products based on the company's proprietary Mucus Penetrating Particle (MPP) platform, today announced the initiation of two clinical trials with its nanotechnology-based loteprednol etabonate MPP (LE-MPP) program, KPI-121. Kala has initiated dosing in its 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. In addition, Kala has initiated a Phase 2 trial (KPI-121-C-002) with KPI-121 to investigate the safety and efficacy of low-dose LE-MPP in patients with dry eye disease.

“We are pleased to advance the clinical development of KPI-121, the first product candidate leveraging Kala’s proprietary MPP delivery platform,” said Guillaume Pfefer, Ph.D., President and Chief Executive Officer of Kala. “Kala is a pioneer in the application of nanotechnology to ophthalmology. Our goal is to leverage the power of our Mucus Penetrating Particle technology to develop new and better treatments for multiple ocular diseases. We believe that nanotechnology has the potential to transform the treatment of eye diseases in much the same way it has already transformed other therapeutic areas.”

Kala’s proprietary MPP nanotechnology platform allows therapeutic agents to pass through the mucus layer of the tear film, facilitating penetration into deeper tissues of the eye, including the cornea, aqueous humor and retina.

“Ocular pain and inflammation is a significant issue among patients living with dry eye disease, as well as those who have undergone cataract surgery; rapid and efficient treatment for this inflammation is paramount,” said Terry Kim, M.D., Professor of Ophthalmology at Duke University. “Kala’s preclinical data demonstrate that the MPP technology can enhance the pharmacokinetic properties of existing therapeutics to improve penetration to various tissues of the eye. I look forward to continuing to work with Kala on these trials, and am excited about the potential for the MPP technology to improve the treatment of ocular disease.”

Phase 3 Clinical Trial to Evaluate LE-MPP Following Cataract Surgery (KPI-121-C-001)

In a Phase 3, double-masked, randomized, controlled trial, Kala will investigate the efficacy and safety of 1% LE-MPP dosed two times daily and 0.25% LE-MPP dosed four times daily as compared to placebo in subjects who have undergone cataract surgery and who require treatment of postoperative anterior ocular inflammation. Kala aims to enroll approximately 375 patients in 25 centers in the U.S.

In preclinical studies, LE-MPP demonstrated a superior pharmacokinetics profile in target tissues compared to currently marketed loteprednol etabonate products. In head-to-head preclinical studies, LE-MPP delivered significantly greater levels of drug to the aqueous humor, as well as the cornea, conjunctiva and retina than either Lotemax® Suspension or Lotemax® Gel, with similar dosing regimens.

Phase 2 Clinical Trial to Evaluate LE-MPP in Dry Eye Disease (KPI-121-C-002)

In a Phase 2, double-masked, randomized, controlled study of LE-MPP, Kala will investigate the safety and efficacy of 0.25% LE-MPP compared to vehicle dosed four times daily in subjects who have a documented clinical diagnosis of dry eye disease. Kala aims to enroll approximately 150 patients in up to 10 centers in the U.S.

Later in 2014, Kala will initiate two additional clinical trials with LE-MPP. The first is a Phase 2 trial with 0.25% LE-MPP versus vehicle dosed four times daily in inflammatory meibomian gland disease (posterior blepharitis). The second is an exploratory trial with 1% LE-MPP and 0.25% LE-MPP dosed four times daily in subjects diagnosed with diabetic macular edema or retinal vein occlusion to evaluate the ability to treat retinal diseases via topical administration. The company continues to advance its novel, small molecule receptor tyrosine kinase inhibitor (RTKi)-MPP program towards a development candidate selection.

About Kala Pharmaceuticals

Kala Pharmaceuticals, Inc. is advancing innovative treatments for ocular diseases addressing significant needs in both front and back of the eye based on the company's proprietary Mucus Penetrating Particle (MPP) platform technology. Kala's topical ocular MPP formulations enhance penetration into ocular tissue by facilitating penetration through the mucus layer of tear film. 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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