Kala Pharmaceuticals Announces IND Submission of its MPP-Formulated Loteprednol Etonbonate (LE-MPP) for Post-Cataract Surgery

Waltham, Mass., January 6, 2014 – Kala Pharmaceuticals, Inc., a leading developer of innovative ophthalmic products based on the Company's proprietary Mucus Penetrating Particle (MPP) technology, announced today that it has submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration to initiate a Phase 3 clinical program with its MPP-formulated loteprednol etabonate ophthalmic nano-suspension product (LE-MPP) for the treatment of post-operative inflammation and pain following cataract surgery.

Kala's proprietary MPP technology platform allows therapeutic agents to pass through the mucus layer of the ocular surface, facilitating penetration into deeper tissues of the eye, including the aqueous humor and retina. Kala's MPPs are designed to potentiate pharmacological effects within target tissues. The objective of the upcoming clinical trial with Kala's LE-MPP product is to demonstrate anti-inflammatory efficacy similar to that of other steroid-based treatments with less frequent (twice-daily) dosing while maintaining the safety profile of current loteprednol etabonate products.

"It's exciting to see nanoparticle technology moving to the forefront of the ophthalmology field. By combining small particle size and state-of-the-art surface engineering techniques, physicians and patients should benefit from a variety of new and improved therapeutic options across ophthalmic disease states," said Terry Kim, MD, Professor of Ophthalmology at Duke University Eye Center.

"In preclinical studies, LE-MPP demonstrated a superior pharmacokinetics profile in target tissues compared to currently marketed loteprednol etabonate products" said Kim Brazzell, Ph.D., Kala's Chief Medical Officer. "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. The objective of the upcoming clinical trial will be to demonstrate if twice-daily administration of 1% LE-MPP is effective in the treatment of inflammation and pain following cataract surgery. If successful, this would represent a significant dosing advantage compared to other topical steroids, which are currently indicated for four times a day dosing."

"The global topical corticosteroid market is significant and growing based on the aging population. A topical corticosteroid with superior penetration and pharmacokinetics and a more favorable dosing regimen would be a welcome alternative to current treatment regimens," said Guillaume Pfefer, Ph.D., Kala's President and Chief Executive Officer. "Beyond the post-surgical program, Kala plans to initiate clinical programs with lower doses of LE-MPP in both dry eye disease and blepharitis in 2014."

About Kala Pharmaceuticals

Kala Pharmaceuticals, Inc. is advancing innovative treatments for ocular diseases addressing significant unmet needs in both front and back of the eye based on the Company's proprietary Mucus Penetrating Particle (MPP) technology. Kala's topical ocular MPP formulations enhance penetration of diverse therapeutic agents into ocular tissue, including those in the back of the eye, by facilitating penetration through the mucus layer of tear film. Kala's product development pipeline includes: a 1% formulation of loteprednol etabonate (1% LE-MPP) to treat post-surgical ocular inflammation and pain, expected to enter a pivotal clinical study in 2014; a 0.25% LE-MPP formulation for dry eye, blepharitis, and retinal disease, expected to enter clinical trials in 2014, and a topically applied receptor tyrosine kinase inhibitor (RTKi-MPP) for the treatment of wet age-related macular degeneration (AMD), which is advancing toward selection of a clinical candidate in 2014.

Kala's approach to penetrating mucus layers also has potential application in other disease areas, such as respiratory, female reproductive tract, and gastrointestinal diseases, and in these areas the Company will seek partners to out-license its breakthrough technology. Kala was founded by leaders in the fields of nanomedicine and biopharmaceutical engineering, maintains an esteemed group of advisors including co-founder and MIT professor Dr. Robert Langer, and is backed by leading investors including Lux Capital, Polaris Venture Partners, Third Rock Ventures, and Crown Venture Fund, LLC**.** For more information, please visit **www.kalarx.com**.

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