Kala Pharmaceuticals Submits New Drug Application to U.S. Food and Drug Administration for INVELTYS™ (KPI-121 1%)

-Kala seeks approval for its topical twice-a-day product candidate for the treatment of inflammation and pain following ocular surgery-

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WALTHAM, Mass., October 25, 2017 – Kala Pharmaceuticals, Inc. (NASDAQ:KALA) today announced that it has submitted a New Drug Application (NDA) to the United States Food and Drug Administration (FDA) for INVELTYS™ (KPI-121 1%), a topical twice-a-day product candidate for the treatment of inflammation and pain in patients who have undergone ocular surgery. If approved, Kala expects INVELTYS would be the first twice-daily ocular corticosteroid indicated for the treatment of post-operative ocular inflammation and pain. The brand name for KPI-121 1%, INVELTYS, has been conditionally approved by the FDA.

INVELTYS utilizes Kala's proprietary Mucus Penetrating Particle (MPP) technology. MPPs are selectively-sized nanoparticles with proprietary coatings that significantly enhance drug penetration and distribution in ocular tissues. In pre-clinical studies, MPPs increased delivery into ocular tissues more than three-fold by facilitating penetration through the tear film mucus.

"INVELTYS administered twice-a-day to patients following cataract surgery demonstrated statistically significant resolution of both inflammation and pain in each of two Phase 3 clinical trials," said Kim Brazzell, Ph.D., Chief Medical Officer of Kala Pharmaceuticals. "Based on these results, as well as its safety profile and twice-daily dosing, we believe that INVELTYS would be a valuable treatment option for doctors and patients."

The NDA filing is supported by positive data from two Phase 3 trials. The first Phase 3 clinical trial was designed to evaluate INVELTYS administered twice-a-day and KPI-121 0.25% administered four times a day for 14 days following cataract surgery. Statistical significance was achieved for the primary efficacy endpoints of complete resolution of inflammation at day 8 maintained through day 15 with no need for rescue medication compared to placebo and complete resolution of pain

at day 8 maintained through day 15 with no need for rescue medications compared to placebo with both INVELTYS and KPI-121 0.25%. In May 2017, Kala announced topline results from the second, confirmatory Phase 3 clinical trial with INVELTYS. Compared to placebo, administration of INVELTYS twice-a-day for 14 days achieved statistical significance for both primary efficacy endpoints of complete resolution of inflammation at day 8 maintained through day 15 with no need for rescue medication compared to placebo and complete resolution of pain at day 8 maintained through day 15 with no need for rescue medications and all secondary endpoints. INVELTYS was found to be well tolerated with no treatment-related serious adverse events observed during the course of either trial.

“The filing of the NDA for INVELTYS marks a major milestone for Kala in advancing our mission of developing treatments for eye conditions using our MPP technology,” said Mark Iwicki, Chairman and Chief Executive Officer of Kala Pharmaceuticals. “We believe that our MPP technology has the potential to not only improve the post-operative care of patients undergoing ocular surgery, but also help advance care in other ophthalmic indications such as dry eye disease using our KPI-121 0.25% product candidate. We expect to receive topline results from the Phase 3 clinical program for KPI-121 0.25% in patients with dry eye disease by the end of 2017.”

About Post-Operative Inflammation and Pain

Ocular inflammation and pain are common complications following ocular surgery. According to Marketscope, in 2016 there were 7.7 million ocular surgeries in the United States, which is projected to grow to up to 9.4 million in 2021. More than half of the ocular surgeries performed in the U.S. are cataract surgeries. Tissue damage caused by ocular surgery leads to the production of prostaglandins, lipids that aid in recovery at the site of an injury, and an increase in blood flow to the affected area, both of which contribute to inflammation. The standard of care for post-operative inflammation and pain includes anti-inflammatory drugs such as corticosteroids, which improve patient comfort and accelerate recovery through disruption of the inflammatory cascade. The current four-times-a-day dosing regimen for corticosteroid treatment can be burdensome for patients as they are taking multiple eye drop products following surgery, and is believed to reduce patient compliance. There are no twice-daily ocular

corticosteroid products currently approved in the U.S. for the treatment of post-operative inflammation and pain.

About INVELTYS™ (KPI-121 1%)

INVELTYS™ (KPI-121 1%) is a twice-a-day corticosteroid for the treatment of inflammation and pain following ocular surgery. INVELTYS utilizes Kala's proprietary Mucus-Penetrating Particle (MPP) technology to enhance penetration into target tissues of the eye. In pre-clinical studies, MPP increased delivery of a corticosteroid into ocular tissues more than three-fold by facilitating penetration through the tear film mucus. INVELTYS has successfully completed two Phase 3 clinical trials and achieved statistiscal significance for both primary efficacy endpoints in both trials. Kala believes INVELTYS has a favorable treatment profile compared to the standard of care for the treatment of inflammation and pain following ocular surgery, due to its twice-a-day dosing regimen and rapid onset of relief. In each of these trials, INVELTYS was well tolerated with no treatment-related serious adverse events observed.

About Kala Pharmaceuticals, Inc.

Kala is a biopharmaceutical company focused on the development and commercialization of therapeutics using its proprietary Mucus-Penetrating Particle (MPP) technology, with an initial focus on the treatment of eye diseases. Kala has applied the MPP technology to a corticosteroid designed for ocular applications, resulting in two product candidates in Phase 3 clinical development, INVELTYS™ (KPI-121 1%) for the treatment of inflammation and pain following ocular surgery and KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, that involve substantial risks and uncertainties including statements regarding the development and regulatory status of the company's product candidates, including INVELTYS™ (KPI-121 1%) for the treatment of inflammation and pain following ocular surgery and KPI-121 0.25% for the temporary relief of the signs and symptoms of dry eye disease. All statements, other than statements of historical facts, contained in this press release, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives

of management, are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. For a discussion of the risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the "Risk Factors" section, as well as discussions of potential risks, uncertainties and other important factors, in our Quarterly Reports on Form 10-Q and other filings we make with the Securities and Exchange Commission. These forward-looking statements should not be relied upon as representing the Company’s views as of any date subsequent to the date of this release. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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