Press Release

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KALA PHARMACEUTICALS ANNOUNCES NEW DRUG APPLICATION FOR INVELTYSTM (KPI-121 1%) HAS BEEN ACCEPTED FOR REVIEW BY THE U.S. FOOD AND DRUG ADMINISTRATION

- INVELTYS expected to be the first twice-daily ocular steroid indicated for the treatment of inflammation and pain following ocular surgery, if approved -

- PDUFA target action date of August 24, 2018 -

WALTHAM, Mass.--(BUSINESS WIRE)--Jan. 5, 2018-- Kala Pharmaceuticals, Inc. (NASDAQ:KALA), a biopharmaceutical company focused on the development and commercialization of product candidates using its proprietary mucus-penetrating particle (MPP) technology, today announced that the New Drug Application (NDA) 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, has been accepted for review by the United States Food and Drug Administration (FDA). The FDA, in its 74-day letter, indicates that the application is sufficiently complete to permit a substantive review and has set a target action date under the Prescription Drug User Fee Act (PDUFA) of August 24, 2018. If approved, INVELTYS is expected to 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.

“All currently marketed steroids for the treatment of post-surgical inflammation and pain are approved with four-times-a-day dosing,” said Dr. Terry Kim, Professor of Ophthalmology and Chief of the Cornea and External Disease Service in the Department of Ophthalmology at Duke University Eye Center. “This regimen can be significantly burdensome for patients. Based on its efficacy and safety results, as well as its unique twice-daily dosing, I believe that if approved, INVELTYS will be an important new treatment option for patients and physicians alike.”

INVELTYS utilizes Kala’s proprietary Mucus Penetrating Particle (MPP) technology. MPPs are selectively-sized nanoparticles with proprietary coatings that Kala believes 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.

The NDA submission for INVELTYS was supported by positive data from two Phase 3 clinical trials, in each of which INVELTYS administered twice-a-day to patients following cataract surgery 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 compared to placebo. INVELTYS was found to be well tolerated with no treatment-related serious adverse events observed during the course of either trial.

“The FDA’s acceptance of the NDA filing for INVELTYS is another significant milestone for the company towards our mission of developing innovative treatments for ocular conditions using our MPP technology,” said Kim Brazzell, Ph.D., Chief Medical Officer of Kala Pharmaceuticals.

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 U.S., 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 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 statistical significance for both primary efficacy endpoints in both trials. In each of these trials, INVELTYS was well tolerated with no treatment-related serious adverse events observed. Kala believes INVELTYS has a favorable 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. A New Drug Application (NDA) for INVELTYS was accepted for review by the U.S. Food and Drug Administration (FDA) with a target action date of August 24, 2018.

About Kala Pharmaceuticals

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 lead product candidates. The product candidates are INVELTYS™ (KPI-121 1%) for the treatment of inflammation and pain following ocular surgery, for which we have submitted an NDA, 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 as a result of various risks and uncertainties including, but not limited to: whether our NDA for INVELTYS will be approved by its PDUFA date or at all; uncertainties inherent in the availability and timing of data from ongoing clinical trials; expectations for regulatory approvals to conduct trials or to market products; whether the Company’s cash resources will be sufficient to fund the Company’s foreseeable and unforeseeable operating expenses and capital expenditure requirements; other matters that could affect the availability or commercial potential of the Company’s product candidates; and other important factors, any of which could cause the Company’s actual results to differ from those contained in the forward-looking statements, discussed in the "Risk Factors" section of 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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