Kala Pharmaceuticals Provides Update on Launch Plans for EYSUVIS™ for the Treatment of Dry Eye Disease

November 16, 2020

-- Poster presentation and promotional activities highlighted at the American Academy of Ophthalmology 2020 Virtual Annual Meeting --
-- On-track to begin shipping EYSUVIS to wholesalers in mid-December --
-- Wholesale Acquisition Cost announced --

WATERTOWN, Mass.--(BUSINESS WIRE)--Nov. 16, 2020-- Kala Pharmaceuticals, Inc., (NASDAQ:KALA), a biopharmaceutical company focused on the discovery, development and commercialization of innovative therapies for diseases of the eye, today provided an update on its plans to launch EYSUVIS (loteprednol etabonate ophthalmic suspension) 0.25% for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease.

“We continue to make significant progress on our plans to launch EYSUVIS and establish it as the preferred, first-line prescription therapy for dry eye disease,” said Todd Bazemore, Chief Operating Officer of Kala Pharmaceuticals. “We have nearly completed the hiring and onboarding of the first wave of our planned sales force expansion ahead of the virtual launch meeting in early December. We have also established a wholesale acquisition cost for EYSUVIS, which will allow us to begin submitting payer contract bids to pharmacy benefit managers (PBMs), commercial and Medicare Part D plans. We have expanded on our educational and marketing activities, including data presentations and promotional events at the recent American Academy of Ophthalmology 2020 Virtual Annual Meeting. We expect to begin shipping EYSUVIS to wholesalers in mid-December and look forward to delivering EYSUVIS to eye care professionals and patients by the end of the year.”

Kala continues to make significant progress in launch preparations for EYSUVIS since its approval by the U.S. Food and Drug Administration (FDA) on October 26, 2020. Educational activities were initiated at the American Academy of Ophthalmology (AAO) 2020 Virtual Meeting, held from November 13-15, 2020. Aggregate data from four clinical trials evaluating EYSUVIS for the treatment of dry eye disease, including three Phase 3 trials and one Phase 2 trial, were presented in a poster presentation by Edward Holland, M.D., Director of Cornea Services at Cincinnati Eye Institute and Professor of Ophthalmology at the University of Cincinnati. Promotional activities at AAO also included a virtual booth highlighting the product’s approval and upcoming availability, daily sponsored educational programs in the Industry Showcase, and a sponsored webinar hosted by the AAO Foundation.

Kala has nearly completed the hiring and onboarding of an expanded team of sales professionals who have on average more than seven years of ophthalmic sales experience and more than 14 years of pharmaceutical sales experience. At launch, Kala will have approximately 90 sales professionals and it plans to grow the sales force to approximately 125 sales representatives in 2021, pending the status of the COVID-19 pandemic. Over 90 percent of the sales force has eyecare experience, and more than half have experience in dry eye disease. A virtual launch meeting is planned for early December 2020 with promotional activities set to begin by year end. The Company expects to begin shipping EYSUVIS to wholesalers by mid-December.

The Wholesale Acquisition Cost (WAC or “list price”) for a 10 mL bottle of EYSUVIS has been set at $465. The list price is not inclusive of discounts to payers, providers, distributors and other purchasing organizations. The out-of-pocket cost to a patient will depend upon insurance coverage, copay, and eligibility for participation in the patient assistance program.

As of September 30, 2020, Kala had cash, cash equivalents and short-term investments of $159.1 million. Kala anticipates that its existing cash, cash equivalents and short-term investments, along with anticipated sales of INVELTYS®, will enable it to fund its operations into at least the third quarter of 2022. Kala expects revenue anticipated to be generated from sales of EYSUVIS will provide additional cash runway.

About EYSUVIS:

EYSUVIS (loteprednol etabonate ophthalmic suspension) 0.25% is approved for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease. EYSUVIS utilizes Kala's AMPPLIFY mucus-penetrating particle (MPP) Drug Delivery Technology to enhance penetration of loteprednol etabonate (LE) into target tissue of the ocular surface. EYSUVIS was approved by the FDA on October 26, 2020. Kala believes that EYSUVIS' broad mechanism of action, rapid onset of relief of both signs and symptoms, favorable tolerability and safety profile and the potential to be complementary to existing therapies, offer a differentiated product profile for the short-term treatment of dry eye disease, including the management of dry eye flares.

EYSUVIS, as with other ophthalmic corticosteroids, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures. The initial prescription and each renewal of the medication order should be made by a physician only after examination of the patient with the aid of magnification, such as slit lamp biomicroscopy, and, where appropriate, fluorescein staining. Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, as well as defects in visual acuity and fields of vision. Corticosteroids should be used with caution in the presence of glaucoma. Renewal of the medication order should be made by a physician only after examination of the patient and evaluation of the IOP. Use of corticosteroids may result in posterior subcapsular cataract formation. Use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, corticosteroids may mask infection or enhance existing infection. Use of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular corticosteroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local corticosteroid application. Fungus invasion must be considered in any persistent corneal ulceration where a corticosteroid has been used or is in use. The most common adverse drug reaction following the use of EYSUVIS for two weeks was instillation site pain, which was reported in 5% of patients.

Please see full Prescribing Information at www.eysuvis.com

About Kala Pharmaceuticals, Inc.

Kala is a biopharmaceutical company focused on the discovery, development, and commercialization of innovative therapies for diseases of the eye. Kala has applied its AMPPLIFY® mucus penetrating particle Drug Delivery Technology to a corticosteroid, loteprednol etabonate (LE), designed for ocular applications, resulting in the October 2020 approval of EYSUVIS™ (loteprednol etabonate ophthalmic suspension) 0.25% for the short-term (up to two weeks) treatment of signs and symptoms of dry eye disease and the January 2019 launch of INVELTYS® (loteprednol etabonate ophthalmic suspension) 1% for the treatment of post-operative inflammation and pain following ocular surgery.

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 Company's expectation to begin shipping EYSUVIS to wholesalers by mid-December 2020 and delivering EYSUVIS to eye care professionals and patients by the end of the year, the Company's plan to grow to 125 sales representatives in 2021, pending the status of the COVID-19 pandemic, and the Company's expectations regarding its use of cash, cash runway and projected revenues. All statements, other than statements of historical facts, contained in this press release, including statements regarding the Company's strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "continue" "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The Company may not actually achieve the plans, intentions or expectations disclosed in its forward-looking statements, and you should not place undue reliance on such 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: the impact of extraordinary external events, such as the current pandemic health event resulting from the novel coronavirus (COVID-19), and their collateral consequences, including disruption of the activities of our sales force and the market for EYSUVIS and INVELTYS; whether the Company will be able to successfully implement its commercialization plans for EYSUVIS and INVELTYS; whether the market opportunity for EYSUVIS and INVELTYS is consistent with the Company's expectations and market research; the Company's ability execute on the commercial launch of EYSUVIS on the timeline expected, or at all; whether the Company will be able to generate its projected net product revenue on the timeline expected, or at all; whether the Company's cash resources will be sufficient to fund the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements for the Company's expected timeline; other matters that could affect the availability or commercial potential of EYSUVIS, INVELTYS and 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 the Company's Annual Report on Form 10-K, most recently filed Quarterly Report on Form 10-Q and other filings the Company makes with the Securities and Exchange Commission. These forward-looking statements represent the Company's views as of the date of this release and should not be relied upon as representing the Company's views as of any date subsequent to the date hereof. The Company does 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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