Kala Pharmaceuticals Announces FDA Acceptance of New Drug Application for EYSUVIS™ for Dry Eye Disease

May 26, 2020

-- FDA Sets PDUFA Goal Date of October 30, 2020 --

WATERTOWN, Mass.--(BUSINESS WIRE)--May 26, 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 announced that the U.S. Food and Drug Administration (FDA) has accepted for review the company's New Drug Application (NDA) resubmission for EYSUVIS (loteprednol etabonate ophthalmic suspension) 0.25%, its product candidate for the short-term treatment of the signs and symptoms of dry eye disease. The FDA stated that the NDA resubmission is a complete, Class 2 response to the Complete Response Letter (CRL) issued in August 2019, and the FDA set a Prescription Drug User Fee Act (PDUFA) goal date of October 30, 2020 for the completion of its review of the NDA.

"The FDA's acceptance of our NDA resubmission signifies critical progress toward our goal of delivering EYSUVIS as the first prescription medicine for the short-term treatment of dry eye disease," said Kim Brazzell, Ph.D., Chief Medical Officer of Kala Pharmaceuticals. "We are very appreciative that the Agency set a standard Class 2 review timeline, despite the ongoing pandemic, and we look forward to working together through their review of our NDA submission."

Kala resubmitted the EYSUVIS NDA in April 2020, in response to the CRL it received from the FDA in August 2019, which indicated that positive data from an additional clinical trial was needed to support a resubmission of the NDA. The positive results from STRIDE 3 for both signs and symptoms of dry eye disease, along with the positive data from the previous clinical trials of EYSUVIS, served as the basis for Kala's NDA resubmission package. As announced in March 2020, STRIDE 3, a Phase 3 clinical trial of EYSUVIS, met both of its primary symptom endpoints, demonstrating a statistically significant improvement in ocular discomfort severity in both the overall intent-to-treat (ITT) population and in a predefined subgroup of ITT patients with more severe ocular discomfort at baseline. Additionally, statistical significance was achieved in the key secondary endpoints of conjunctival hyperemia at day 15 in the ITT population and ocular discomfort severity at day 8 in the ITT population. Significant results were also observed for total corneal staining at day 15 in the ITT population. Consistent with prior clinical experience, EYSUVIS was well-tolerated in STRIDE 3, with adverse events and intraocular pressure increases comparable to vehicle.

About EYSUVIS™

Kala is developing EYSUVIS (loteprednol etabonate ophthalmic suspension) 0.25% for the short-term treatment of the signs and symptoms of dry eye disease. Dry eye disease is a chronic, episodic, multifactorial disease affecting the tears and ocular surface and can involve tear film instability, inflammation, discomfort, visual disturbance and ocular surface damage. EYSUVIS utilizes Kala's AMPPLIFY™ mucus-penetrating particle (MPP) Drug Delivery Technology to enhance penetration of loteprednol etabonate (LE) into target tissues of the eye. Kala has completed one Phase 2 and three Phase 3 clinical trials, STRIDE 1, STRIDE 2 and STRIDE 3 (STRIDE - Short Term Relief In Dry Eye) for EYSUVIS. Kala believes that the broad mechanism of action of EYSUVIS, rapid onset of relief of both signs and symptoms and favorable tolerability and safety profile combine for a strong profile to treat Dry Eye Disease. In addition, the potential for EYSUVIS to be used both as a first line prescription medicine and complementary to existing therapies, could result in a preferred profile for the short-term treatment of dry eye disease, including the management of dry eye flares and other dry eye associated conditions.

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 January 2019 launch of INVELTYS® (loteprednol etabonate ophthalmic suspension) 1% and its investigational product candidate, EYSUVIS™ (loteprednol etabonate ophthalmic suspension) 0.25%, for which a New Drug Application (NDA) is under review by the United States Food and Drug Administration (FDA) with a target action date under the Prescription Drug User Fee Act (PDUFA) set for October 30, 2020.

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 lead product candidate, EYSUVIS, for the short-term 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 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 INVELTYS and any delay in timing of regulatory review of the NDA for EYSUVIS; whether the Company will be able to successfully implement its commercialization plans for INVELTYS and EYSUVIS, if approved; whether the market opportunity for INVELTYS and EYSUVIS is consistent with the Company's expectations and market research; whether any additional clinical trials will be initiated or required for EYSUVIS prior to approval of the

NDA, or at all, and whether the NDA for EYSUVIS will be approved on the timeline expected, or at all; the Company's ability execute on the commercial launch of EYSUVIS, if and when approved, 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 INVELTYS and the Company's product candidates, including EYSUVIS; 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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