# Kala Pharmaceuticals Announces Availability of EYSUVIS™ for the Treatment of Dry Eye Disease and Provides Update on Development Pipeline

January 7, 2021

*-- First and only prescription therapy approved specifically for short-term treatment of the signs and symptoms of dry eye disease now available in pharmacies nationwide --*

*-- Advancing multiple NCE development programs targeted to address front and back of eye diseases --*

WATERTOWN, Mass.--(BUSINESS WIRE)--Jan. 7, 2021-- 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 the launch of 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. EYSUVIS is now available in national and regional U.S. pharmaceutical distribution centers. Patients with a prescription can access EYSUVIS through their local retail pharmacies or through home delivery.

Kala has completed the hiring and onboarding of its expanded ophthalmology sales force, which now consists of 91 sales professionals calling on eyecare professionals, including ophthalmologists and optometrists. The Company plans to expand its sales force to approximately 125 sales representatives in 2021, pending the status of the COVID-19 pandemic. In addition, Kala's payor account team is actively engaged in contract discussions with Commercial and Medicare Part D health plans.

"We are excited to announce our second product launch in two years, with EYSUVIS now available in the United States as the first approved prescription therapy specifically indicated for the short-term treatment of dry eye disease," said Mark Iwicki, Chairman, President and Chief Executive Officer of Kala Pharmaceuticals. "We are looking forward to bringing this important new therapy to the millions of dry eye disease patients who suffer from episodic flares but did not have an FDA-approved rapid-acting, prescription treatment option prior to EYSUVIS. As we execute against our strategy to establish EYSUVIS as the preferred, first-line prescription therapy for dry eye disease, we continue to promote INVELTYS® as the first and only twice daily corticosteroid for post-operative inflammation and pain following ocular surgery, while also advancing Kala's next wave of pre-clinical development programs in our pipeline."

Kala is progressing its pipeline of pre-clinical development programs targeted to address front and back of the eye diseases. These programs, all of which are new chemical entities (NCEs), include: (1) a receptor Tyrosine Kinase Inhibitor program (rTKI), for the treatment of retinal diseases, including wet age-related macular degeneration (Wet AMD); (2) selective glucocorticoid receptor modulators (SEGRMs), which are a novel class of therapies designed to modify the downstream activity of the receptors to exhibit the anti-inflammatory and immunomodulatory properties of corticosteroids while potentially avoiding the typical safety concerns of steroids; and (3) novel steroids designed to target the ocular surface and thus have the potential to be a safer alternative to traditional topical steroids. Kala owns all intellectual property and worldwide rights to these pipeline candidates.

Although the Company has not finalized its full financial results for the fourth quarter and fiscal year ended December 31, 2020, it expects to report cash, cash equivalents and short-term investments of approximately $153.5 million as of December 31, 2020. Preliminary cash, cash equivalents and short-term investments include net proceeds generated from the sale of shares of Common Stock under the Company's "at-the-market" offering program during the fourth quarter of 2020. Kala anticipates that its cash, cash equivalents and short-term investments as of December 31, 2020, along with anticipated sales of INVELTYS, will enable it to fund its operations into at least the fourth 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 proprietary 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 treatment of dry eye disease, including the management of dry eye flares.

**EYSUVIS Important Safety Information**

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 (MPP) Drug Delivery Technology to two ocular therapies, 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 INVELTYS® (loteprednol etabonate ophthalmic suspension) 1% for the treatment of post-operative inflammation and pain following ocular surgery. The Company also has a pipeline of pre-clinical development programs targeted to address unmet medical needs, including both front and back of the eye diseases. For more information on Kala, please visit www.kalarx.com.

**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 plan to grow its sales force to 125 sales representatives in 2021, pending the status of the COVID-19 pandemic; the status of insurance coverage and the availability of reimbursements for EYSUVIS and INVELTYS for commercial and Medicare Part D patients; the commercial potential for EYSUVIS and INVELTYS; Kala's plans to advance its preclinical pipeline of programs and the potential benefits of such programs; 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 the Company's 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, including obtaining Commercial and Medicare Part D payor coverage; 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 and INVELTYS; 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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