Kala Pharmaceuticals Announces New Commercial and Medicare Coverage for EYSUVIS®

May 3, 2022

--Now Covered by the largest Pharmacy Benefit Manager in the United States and Humana Medicare--
--Expands Commercial coverage to 92% of total commercial lives--
--Doubles Medicare coverage from 7.1 million lives to 14.1 million lives--

ARLINGTON, Mass., May 03, 2022 (GLOBE NEWSWIRE) -- Kala Pharmaceuticals, Inc., (NASDAQ:KALA), a commercial-stage biopharmaceutical company focused on the discovery, development and commercialization of innovative therapies for diseases of the eye, today announced that the largest Pharmacy Benefit Manager in the United States has added EYSUVIS (loteprednol etabonate ophthalmic suspension) 0.25% as a covered brand on its commercial formularies, effective May 1, 2022. This adds 28.5 million commercial lives to EYSUVIS coverage, bringing total commercial coverage to 155.3 million lives, or 92% of total commercial lives.

Also today, Kala announced that Humana, one of the largest Medicare health plans in the United States, has added EYSUVIS as a Preferred Brand on its Medicare formularies, effective June 1, 2022. This adds approximately 7 million Medicare lives to EYSUVIS coverage, bringing total EYSUVIS Medicare coverage to 14.1 million lives, or approximately 30% of all Medicare lives.

“We are excited to announce this additional payer coverage, which brings our commercial access to 92% of covered lives and doubles our Medicare Part D coverage. This is an important step toward our goal of securing broad commercial and Medicare access for EYSUVIS and we expect the additional coverage will translate into higher prescription fulfillment rates and accelerated growth,” said Todd Bazemore, President and Chief Operating Officer of Kala Pharmaceuticals. “Earlier this year, we secured coverage with several large commercial and Medicare Part D plans and, together with these additions, we have now achieved total EYSUVIS coverage for more than 169 million lives. We continue to engage with other commercial and Medicare Part D health plans and anticipate further formulary additions in 2022.”

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. In preclinical studies, the AMPPLIFY Drug Delivery Technology increased delivery of LE into target ocular tissues more than three-fold compared to an active LE comparator by facilitating penetration through the tear film mucins. 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 commercial-stage 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% and INVELTYS® (loteprednol etabonate ophthalmic suspension) 1%. Kala also has a pipeline of development programs including a clinical-stage secretome product candidate, KPI-012, initially targeting persistent corneal epithelial defects (PCED) and multiple proprietary new chemical entity (NCE) preclinical 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. Any statements in this press release about Kala’s future expectations, plans and prospects, including but not limited to statements regarding the addition of Commercial and Medicare coverage translating into higher prescription fulfillment rates and accelerating EYSUVIS growth, Kala’s anticipation with respect to additional formulary additions in 2022, and other statements containing the words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “likely,” “will,” “would,” “could,” “should,” “continue,” and similar expressions constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: 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 Kala’s sales force and the market for

EYSUVIS and INVELTYS; whether Kala will be able to successfully implement its commercialization plans for EYSUVIS and INVELTYS; whether the market opportunity for EYSUVIS and INVELTYS is consistent with Kala's expectations and market research; Kala's ability execute on the commercial launch of EYSUVIS on the timeline expected, or at all, including obtaining and increasing Commercial and Medicare Part D payor coverage; whether Kala will be able to generate its projected net product revenue on the timeline expected, or at all; Kala's ability to realize the anticipated benefits of the acquisition of Combangio, Inc. ("Combangio") including the possibility that the expected benefits, synergies and growth prospects from the acquisition of Combangio will not be realized or will not be realized within the expected time period or at all, the uncertainties inherent in the initiation and conduct of clinical trials, availability and timing of data from clinical trials, whether results of early clinical trials or trials in different disease indications will be indicative of the results of ongoing or future trials, whether results of the Phase 1b clinical efficacy trial of KPI-012 will be indicative of results for any future clinical trials and studies of KPI-012, uncertainties associated with regulatory review of clinical trials and applications for marketing approvals, whether regulatory or commercial milestones are achieved, Kala's ability to successfully integrate KPI-012 into its business, Kala's ability to retain and hire key personnel, the risk that disruption resulting from the integration of KPI-012 may adversely affect its business and business relationships, including with employees and suppliers, the sufficiency of cash resources and need for additional financing and other important factors, any of which could cause the Kala's actual results to differ from those contained in the forward-looking statements, discussed in the "Risk Factors" section of Kala's Annual Report on Form 10-K, most recently filed Quarterly Report on Form 10-Q and other filings Kala makes with the Securities and Exchange Commission. These forward-looking statements represent Kala's views as of the date of this release and should not be relied upon as representing Kala's views as of any date subsequent to the date hereof. Kala 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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