Kala Announces Entry into Definitive Agreement to Sell EYSUVIS® and INVELTYS® to Alcon Inc.

May 23, 2022

--Kala Will Receive $60 Million in Upfront Payment; Eligible to Receive Additional Sales-Based Milestone Payments--
--Kala Will Focus Resources on Phase 2/3 Trial of KPI-012 for Orphan Disease Persistent Corneal Epithelial Defect--

ARLINGTON, Mass., May 23, 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 it has entered into a definitive agreement to sell its commercial portfolio and related intellectual property assets to Alcon Inc. This includes EYSUVIS, the first and only U.S. Food and Drug Administration (FDA) approved medicine for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease, and INVELTYS, a twice-a-day corticosteroid for the treatment of post-operative inflammation and pain following ocular surgery.

“The sale of EYSUVIS and INVELTYS is an important step as we execute on our strategic plan and pursue our mission of delivering innovative therapies that can address significant unmet needs in ophthalmology,” said Mark Iwicki, Chief Executive Officer and Chairman of Kala. “Alcon is an ideal partner to expand the reach of our commercial assets. Alcon has a decades-long history of delivering market-leading vision care to patients around the world and benefits from robust franchises in dry eye disease and surgical care, making them deeply familiar with eye care professionals and the patients EYSUVIS and INVELTYS are intended to treat. We look forward to working with Alcon through this transition and, ultimately, to devoting our internal resources to developing innovative therapies, including KPI-012, to further transform the treatment of eye diseases.”

Kala plans to focus on developing KPI-012, a novel cell-free secretome therapy that has the potential to address a number of rare and severe ocular diseases. Subject to the submission and clearance of an investigational new drug application for KPI-012, Kala expects to initiate a Phase 2/3 clinical trial of KPI-012 for persistent corneal epithelial defect (PCED) in the fourth quarter of 2022 and plans to expand its development program for KPI-012 into additional front and back of the eye indications, with additional details forthcoming in the months ahead. Following the closing of the sale of its commercial assets, Kala expects to realize a substantial reduction in operating expenses, which together with the net proceeds from the upfront cash payment received from this transaction, will extend Kala’s operating cash runway into the second quarter of 2024, beyond the expected KPI-012 Phase 2/3 data readout.

Under the terms of the asset purchase agreement, Kala will receive an upfront payment of $60 million and will be eligible to receive commercial-based sales milestone payments. Kala anticipates the transaction will close in the third quarter of 2022, subject to certain conditions, including the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and other customary closing conditions.

Piper Sandler acted as the exclusive financial advisor, and Wilmer Cutler Pickering Hale and Dorr LLP served as legal counsel to Kala.

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 INVELTYS:
INVELTYS (loteprednol etabonate ophthalmic suspension) 1% is a twice-a-day corticosteroid for the treatment of post-operative inflammation and pain following ocular surgery. INVELTYS utilizes Kala’s proprietary AMPPLIFY mucus-penetrating particle (MPP) Drug Delivery Technology to enhance penetration of loteprednol etabonate (LE) into target tissues of the eye. 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. INVELTYS was approved by the FDA on August 22, 2018. Kala believes INVELTYS has a favorable profile for the treatment of inflammation and pain following ocular surgery, due to its twice-a-day dosing regimen.

INVELTYS, 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. A prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. If this product is used for 10 days or longer, IOP should be monitored. Use of corticosteroids may result in posterior subcapsular cataract formation. Use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and 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 suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids 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 steroids 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 steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. In clinical trials, the most common adverse drug reactions were eye pain (1%) and posterior capsular opacification (1%). These reactions may have been the consequence of the surgical procedure.

Please see full Prescribing Information at www.inveltys.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%. The Company 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 about Kala's ability to consummate the transaction with Alcon, primarily focusing its resources on the development of innovative therapies, including KPI-012, and reducing costs, Kala's plans to expand its development program for KPI-012 to address additional front and back of the eye diseases, the sufficiency of Kala's cash resources 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: Kala's ability to consummate the transaction with Alcon; Kala's ability to realize the anticipated benefits of the transaction with Alcon, including the uncertainty regarding the receipt of any milestone payments; the potential for negative effects of the announcement of the transaction with Alcon ; the risk of litigation and/or regulatory actions related to the transaction with Alcon; 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; the uncertainties inherent in the initiation and conduct of preclinical studies and clinical trials; availability and timing of data from clinical trials; uncertainties associated with regulatory review of clinical trials and applications for marketing approvals; whether regulatory or commercial milestones are achieved; the risk that disruption resulting from the announcement of the Alcon transaction 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 the 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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