Kala Pharmaceuticals Acquires Combangio, Expanding its Pipeline with a Clinical-Stage Novel Biologic for the Treatment of Persistent Corneal Epithelial Defect (PCED) and other Rare Ocular Surface Diseases

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-- KPI-012 is a novel secretome with a multifactorial mechanism of action for development in PCED and other orphan ocular surface diseases driven by impaired corneal healing --
-- KPI-012 demonstrated positive safety and efficacy results in PCED Phase 1b clinical trial --
-- Kala expects to initiate Phase 2/3 trial in 3Q 2022 --
--Mark S. Blumenkranz, M.D., Professor Emeritus in the Department of Ophthalmology at Stanford University, appointed to Kala's Board of Directors --
-- Management to host conference call at 10:30 a.m. ET today --

WATERTOWN, Mass., Nov. 15, 2021 (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 acquired Combangio, Inc., a private, clinical-stage company developing regenerative biotherapies for severe ocular surface diseases. Combangio is developing CMB-012, a novel investigational secretome therapy, now known as KPI-012, to address the complex wound healing process in persistent corneal epithelial defect (PCED) and other severe ocular diseases driven by impaired corneal healing.

"Today's acquisition marks a pivotal moment for Kala and a meaningful acceleration toward our goal of strengthening Kala's pipeline for the treatment of front and back of the eye diseases," said Mark Iwicki, Chief Executive Officer of Kala. "KPI-012 is a highly innovative product, which leverages a multifactorial mechanism of action to address the complex process of healing severe corneal defects. KPI-012 is currently in development for PCED, with potential application across a wide range of orphan diseases of the eye. This product candidate is a natural fit with our R&D and commercial expertise, and along with our internal pipeline provides an additional opportunity to leverage our deep ophthalmic expertise to address substantial, underserved markets. We are excited to have completed the acquisition of Combangio and look forward to working alongside their talented team to integrate KPI-012 into our portfolio and ultimately deliver this therapy to transform the treatment of rare ocular surface diseases."

KPI-012 is a novel bone marrow-derived mesenchymal stem cell (MSC) secretome comprised of biomolecules secreted by MSCs, including protease inhibitors, growth factors and neurotrophic factors, processed into a topical ocular solution. KPI-012 is currently in clinical development for the treatment of PCED, which is defined as a persistent non-healing corneal defect or wound that is refractory to conventional treatments. It is a rare disease with an estimated incidence in the U.S. of 100,000 cases and 238,000 cases in the U.S., E.U. and Japan combined and KPI-012 has received Orphan Designation for the treatment of PCED by the U.S. Food and Drug Administration (FDA). PCED can have various etiologies including neurotrophic keratitis, epithelial debridement, microbial/viral keratitis, corneal transplant, limbal stem cell deficiency and trauma, and can lead to corneal ulceration, perforation, scarring, infection and significant vision loss.

In a Phase 1b clinical trial, seven of eight PCED patients treated with KPI-012 twice-daily showed improvement in their PCED, with six of the eight achieving complete healing during the treatment period, which ranged from one to eight weeks. Four of eight patients had complete healing within one week of treatment with the other two that achieved complete healing doing so within two to four weeks of initiation of treatment with KPI-012. All six of the healed patients remained healed through the end of follow-up, which ranged between eight and 19 weeks. There was also significant pain relief in the six patients who reported pain at baseline, with all six achieving a zero-pain score within three weeks of initiation of dosing with KPI-012. KPI-012 was well-tolerated in the trial with no treatment-related safety issues observed.

"KPI-012 is an exciting addition to the Kala pipeline and is an important component of our strategy to develop novel therapies for significant unmet needs in ophthalmic diseases. People living with severe ocular surface diseases are in desperate need of new and better therapeutic options to not only provide symptomatic relief but to avoid the potential vision-threatening consequences of these diseases," said Kim Brazzell, Ph.D., Chief Medical Officer of Kala. "The Phase 1b clinical data are very encouraging for PCED as well as for other rare ocular diseases that involve impaired corneal wound healing. We look forward to working together with our extensive network of corneal specialists to advance this program through clinical development and regulatory approval."

Clinical Development Plan for KPI-012 in PCED

Kala plans to submit an investigational new drug (IND) application to the FDA and, subject to regulatory clearance, initiate a Phase 2/3 trial of KPI-012 in the third quarter of 2022. Kala believes this trial could serve as the first of two required pivotal trials. The FDA has granted KPI-012 orphan drug designation for the treatment of PCED and the Company believes KPI-012 should meet the criteria for fast-track and breakthrough designations.

In addition to PCED, Kala is evaluating other orphan diseases driven by impaired corneal wound healing, such as thermal/chemical injury, corneal ulcers, ocular graft *vs* host disease, Stevens-Johnson syndrome and limbal cell deficiency, and is looking to initiate clinical evaluation for an additional indication after the IND submission and initiation of the PCED trial.

Board and Management Appointments

In conjunction with the acquisition, Mark S. Blumenkranz, M.D., Chairman of Combangio, has been appointed to the Kala Board of Directors, and Darius Kharabi, President and Chief Executive Officer of Combangio, has been appointed as Chief Business Officer of Kala, both effective November 15, 2021.

Mark S. Blumenkranz, M.D.

“I am delighted to join the Kala Board of Directors and look forward to working with the team in its ongoing efforts to advance Kala’s pipeline of innovative therapies for ocular diseases,” said Dr. Blumenkranz. “As an ophthalmologist, I am acutely aware of the unmet needs that continue to exist in the treatment of eye diseases and committed to supporting the development of innovative new medicines that can deliver better outcomes to patients. I have been excited about the potential of KPI-012 for many years and I am eager to partner with the Kala team, both to continue advancing this asset, and to support the development of Kala’s broader pipeline of programs for the front and back of the eye diseases.”

Dr. Blumenkranz is an ophthalmologist and vitreoretinal surgeon who is Chairman and CEO of Kedalion Therapeutics. He is also H.J. Smead Professor Emeritus in the Department of Ophthalmology at Stanford University where he served as Chairman from 1997 to 2015. He is an internationally known vitreo-retinal specialist, with notable contributions in the area of new laser systems, novel pharmaceuticals for macular diseases, ocular gene therapy and ophthalmic tele-health and technology development. Over the course of his career, Dr. Blumenkranz held leadership roles at Oculex Pharmaceuticals (acquired by Allergan), Macusight (acquired by Santen), Peak Surgical (acquired by Medtronics), Optimedica (acquired by AMO), and Oculeve (acquired by Allergan), as well as Adverum, where he served as both co-founder and Chairman of the Board. He is also co-founder and served as a director of Verana Health for ten years, and currently serves as Managing Director of Lagunita Biosciences, a biotechnology and medical investment company and incubator in Menlo Park California.. Dr. Blumenkranz received his Undergraduate, Master’s in Biochemical Pharmacology, and M.D. at Brown University, completed his Ophthalmic residency training at Stanford University, and his Fellowship in vitreo-retinal diseases at the Bascom Palmer Eye Institute.

Darius Kharabi, J.D., M.B.A

“On behalf of my colleagues at Combangio, we are extremely excited to join forces with Kala to accelerate the development of KPI-012 and deliver this novel therapy to people living with severe ocular surface diseases, beginning with PCED. Kala has the R&D and commercial expertise, as well as the established relationships with eye care professionals, to advance this program successfully through development and to market,” said Darius Kharabi, President and Chief Executive Officer of Combangio. “I look forward to working with the Kala leadership team in my new role as Chief Business Officer to help improve outcomes and quality of life for people suffering from debilitating ocular diseases.”

Mr. Kharabi is the President and Chief Executive Officer of Combangio, as well as the co-founder of Lagunita Biosciences LLC, a biotechnology and medical investment company and incubator. He previously served in executive management for xCella and Kedalion, two Lagunita portfolio companies, helping to build early value, raise financing and recruit full-time leadership teams. Prior to Lagunita, he served as Vice President, Corporate Development and International Sales at OrthAlign Inc., a commercial stage orthopedic surgery navigation company, where his responsibilities included the launch of the KneeAlign® total knee arthroplasty navigation product line in North America, Europe, Asia and Australia. Mr. Kharabi started his career as a biotechnology licensing attorney at Wilson, Sonsini Goodrich & Rosati PC. He received his B.S. in Biochemistry from Georgetown University and his J.D. and M.B.A. degrees from Stanford University.

Transaction Terms

Under the terms of the agreement, Kala acquired all of the outstanding equity of Combangio, and the former Combangio equityholders are entitled to receive an upfront payment of an aggregate of $5.0 million in cash, subject to customary adjustments, and an aggregate of 7,788,667 shares of Kala common stock with an aggregate value of approximately $16,122,541, consisting of (i) an aggregate of 6,815,129 shares of common stock to be issued on January 3, 2022 and (ii) an aggregate of 973,538 shares of common stock that will be held back by Kala and will be issuable fifteen months after the closing of the transaction and will serve as partial security for the satisfaction of indemnification obligations and other payment obligations of the former Combangio equityholders. The aggregate value of the post-closing stock consideration was calculated using the closing price of Kala’s common stock on the Nasdaq Global Select Market on November 12, 2021, the last trading day prior to the closing. The former Combangio equityholders are also entitled to receive up to an aggregate of $105 million in cash and Kala stock upon the achievement by KPI-012 of specified development, regulatory and sales milestones and tiered royalties on worldwide net sales of KPI-012, if any, at a rate in the mid to high single digits. In addition, the former Combangio equityholders are entitled to receive a percentage rate in the high single digits of any income received by Kala from a commercial out-license of KPI-012.

The Board of both companies have approved the transaction and the transaction closed simultaneously with execution of definitive agreements on November 15, 2021.

Conference Call Information

Kala will host a live conference call and webcast today at 10:30 a.m. ET to discuss its acquisition of KPI-012, as well as its third quarter 2021 financial results, which were announced in a separate press release this morning.

To access the live conference call, please dial 866-300-4091 (domestic) or 703-736-7433 (international) and refer to conference ID 7298039. To access a live webcast including a slide presentation and subsequent archived recording of the call, please visit “Events” in the “Investor” section on the Kala website at http://kalarx.com/.

About Kala Pharmaceuticals

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% 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 development programs including a clinical-stage secretome product candidate initially targeting persistent corneal epithelial defects (PCED) and multiple proprietary NCE preclinical development programs targeted to address unmet medical needs, including both front and back of the eye diseases. Kala plans to submit an investigational new drug application with the FDA for KPI-012 and, subject to regulatory clearance, commence a Phase 2/3 clinical trial for PCED in the United States in third quarter of 2022. For more information on Kala, please visit www.kalarx.com.

About Combangio

Combangio is a clinical-stage biotechnology company focused on developing regenerative biotherapeutics based on mesenchymal stem cell (“MSC”) secretomes. Combangio’s lead product candidate, CMB-012 (which has been renamed KPI-012), for the treatment of persistent corneal epithelial

defect (“PCED”), received orphan drug designation from the U.S. Food and Drug Administration (FDA). PCED is a disease of impaired corneal healing and is a rare disease with an estimated incidence in the United States of approximately 100,000 cases per year. Normal healing after a corneal injury follows a highly regulated process, involving growth factors, cell signaling, proliferation, migration and extracellular matrix remodeling. KPI-012 is a novel secretome-based therapy derived from bone-marrow MSC composed of biologically active components secreted from the MSCs, including protease inhibitors and growth factors, that have been shown to facilitate epithelial healing. KPI-012’s multifactorial mechanism of action offers promise for the treatment of PCED and other ocular surface diseases across various etiologies.

Kala’s 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 acquisition of Combangio and the other transactions contemplated by the acquisition of Combangio and any other statements about future expectations, prospects, estimates and other matters that are dependent upon future events or developments, including statements related to Kala’s expectations with respect to the potential financial impact and benefits of the acquisition of Combangio, expectations with respect to potential advantages of KPI-012, the future development or commercialization of KPI-012, conduct and timelines of clinical trials, the clinical utility of KPI-012 for PCEDs, plans for regulatory filings, the market opportunity for KPI-012 for PCEDs and other indications, plans to pursue research and development of KPI-012 for other indications, the sufficiency of Kala’s existing 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: the impact of extraordinary external events, such as the current pandemic health event resulting from the novel coronavirus (COVID-19), and their collateral consequences, Kala’s ability to realize the anticipated benefits of the acquisition of 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, negative effects of the announcement of the acquisition of Combangio on the market price of Kala’s common stock, significant transaction costs, unknown liabilities, the risk of litigation and/or regulatory actions related to the acquisition of Combangio, 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 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 Combangio’s business into its business, Kala’s ability to retain and hire key personnel, the risk that disruption resulting from the acquisition of Combangio 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 the Company’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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