

ACCESS TO INVESTIGATIONAL MEDICINES PRIOR TO REGULATORY APPROVAL

(EXPANDED ACCESS POLICY)

Combangio, a wholly owned subsidiary of KALA BIO, Inc. (together, the “Company”), is developing biologic therapies utilizing its proprietary mesenchymal stem cell secretome (MSC-S) platform. Our development pipeline includes KPI-012, in clinical development for the treatment of persistent corneal epithelial defect (PCED), a rare disease of impaired corneal healing. We are also evaluating KPI-012 for potential expansion to additional indications for rare eye diseases. To accomplish this mission, we conduct clinical trials to assess the safety and efficacy of our MSC-S product candidates. The data generated from these trials will allow us to potentially obtain the necessary marketing approvals from regulatory bodies such as the U.S. Food and Drug Administration and the European Medicines Agency. For a list of the Company’s clinical trials currently recruiting patients, please visit www.clinicaltrials.gov.

In general, patients obtain access to investigational agents prior to regulatory approval by participating in clinical trials. There may, however, be circumstances in which a patient is facing a serious or life-threatening condition, has exhausted available treatment options, and is unable to participate in a clinical trial. In those cases, regulators may permit companies to provide special access to investigational medicines outside of a clinical trial setting. These situations are often called expanded access programs, but are also referred to as compassionate use, early access, pre-approval access, or emergency use.

At this point in time, we do not offer expanded access to any of our investigational products because the lack of clinical data precludes an assessment of their benefit and risk. We continue to monitor the emerging data from the clinical studies of product candidates in our pipeline. When the clinical data have advanced to the point that the Company, regulatory authorities, and treating physicians are able to assess the potential benefit and risk of expanded access use in individual patients outside the context of a clinical trial, we will consider implementing such a program.

Please refer any questions regarding this policy to ExpandedAccess@Kalarx.com.

For information on available expanded access programs, please visit www.clinicaltrials.gov and search “expanded access programs.” For more information about our ongoing clinical trials, please visit our website at www.kalarx.com or visit www.clinicaltrials.gov.