



## **Kaleido Biosciences and the COPD Foundation Announce a Strategic Collaboration to Advance KB109 into Phase 2 Clinical Trial**

August 10, 2021

### **On track to initiate Phase 2 trial in the first quarter of 2022**

LEXINGTON, Mass., Aug. 10, 2021 (GLOBE NEWSWIRE) -- Kaleido Biosciences, Inc. (Nasdaq: KLDO), a clinical-stage healthcare company with a differentiated, chemistry-driven approach to targeting the microbiome to treat disease and improve human health, today announced a strategic collaboration with the COPD Foundation to study KB109 in patients with chronic obstructive pulmonary disease (COPD). The collaboration will partner Kaleido with the COPD Foundation's leading experts in its Digital Health and Therapeutics Accelerator Network, COPD360Net, to support joint clinical development starting with a Phase 2a trial of KB109, a novel Microbiome Metabolic Therapy (MMT™), in COPD.

An expanding body of research indicates that immune and inflammatory responses in the lung are in part driven by the gut microbiome – via the so-called gut-lung axis – making the gut microbiome a potential therapeutic target in COPD. KB109's clinical potential to target the gut-lung axis and improve outcomes in respiratory viral diseases was demonstrated in a study of mild-to-moderate COVID-19 patients. Its mechanism of action is pathogen agnostic, suggesting it could address a wide range of chronic respiratory diseases driven by inflammation or respiratory infections. COPD is the most prevalent chronic respiratory illness, impacting over 250 million people worldwide, and has limited safe and effective treatment options for the control and prevention of acute exacerbations.

"We are excited to embark on this partnership with the COPD Foundation to work towards our shared mission to bring about innovative therapies for people suffering from COPD," said Dan Menichella, President and Chief Executive Officer of Kaleido. "The previous KB109 COVID-19 trial demonstrated activity against the pathologies associated with respiratory viral infections by modulating the gut microbiome and host immune system. We believe this result warrants clinical investigation of KB109 in COPD patients, and we look forward to initiating a Phase 2a trial early in 2022."

COPD Foundation's President and Chief Scientific Officer Ruth Tal-Singer, PhD added, "At the Foundation, we were excited when we saw the KB109 COVID-19 data because of its potential to improve recovery from viral infections for patients with comorbidities. The COPD burden is projected to increase in the coming decades because of continued exposure to risk factors and the aging population. COPD patients would benefit from an oral therapy that could reduce exacerbations and improve quality of life. We are proud to partner with Kaleido in our continued efforts to find a treatment intervention that is affordable and potentially more efficacious for patients."

Patients with severe Acute Exacerbations in COPD (AECOPDs) often require hospitalization and have an increased mortality risk. COPD is not curable, but treatment can relieve symptoms, improve quality of life and reduce the risk of death. The majority of AECOPDs are triggered by respiratory tract viral or bacterial infections which result in lung microbiome dysbiosis, host immunity dysregulation, and pro-inflammatory cascades. With this collaboration, Kaleido and the COPD Foundation intend to further capitalize on KB109's potential to correct dysbiosis and prevent significant disease burden related to respiratory infections in people with COPD.

### **About Microbiome Metabolic Therapies (MMT™)**

Kaleido's Microbiome Metabolic Therapies, or MMTs, are designed to drive the function and distribution of the microbiome's existing microbes in order to decrease or increase the production of metabolites, or to advantage or disadvantage certain bacteria in the microbiome community. The Company's initial MMT candidates are targeted, synthetic glycans that are orally administered, have limited systemic exposure, and are selectively metabolized by enzymes in the microbiome. Kaleido utilizes its discovery and development platform to study MMTs in microbiome samples to rapidly advance MMT candidates rapidly into clinical studies in healthy subjects and patients. These human clinical studies are conducted under regulations supporting research with food, evaluating safety, tolerability and potential markers of effect. For MMT candidates that are further developed as therapeutics, the Company conducts clinical trials under an Investigational New Drug (IND) or regulatory equivalent outside the U.S., and in Phase 2 or later development.

### **About Kaleido Biosciences**

Kaleido Biosciences is a clinical-stage healthcare company with a differentiated, chemistry-driven approach to targeting the microbiome to treat disease and improve human health. The Company has built a proprietary product platform to enable the rapid and cost-efficient discovery and development of novel Microbiome Metabolic Therapies (MMT™). MMTs are designed to modulate the metabolic output and profile of the microbiome by driving the function and distribution of the gut's existing microbes. Kaleido is advancing a broad pipeline of MMT candidates with the potential to address a variety of diseases and conditions with significant unmet patient needs. To learn more, visit <https://kaleido.com/>.

### **About the COPD Foundation**

The COPD Foundation is a not-for-profit organization that was established to improve the lives of people with COPD, bronchiectasis, and nontuberculous mycobacterial (NTM) lung disease through initiatives that expand services and speed innovations that will make treatment more effective and affordable. The Foundation does this through scientific research, education, advocacy, and awareness with the goal of disease prevention, slowed progression, and ultimately a cure. The COPD Foundation leadership and Medical and Scientific advisory committee include representatives of the lung community, clinical science, genetics, and the social sciences (bioethics, economics, and/or law). To learn more, visit the COPD Foundation [website](#) or follow the Foundation on [LinkedIn](#) and [Twitter](#).

### **About COPD360Net**

[COPD360Net's](#) mission is to support the development and adoption of novel digital health tools, medical devices, and therapeutics that treat COPD,

bronchiectasis, and NTM lung disease. This network consists of the core COPD Foundation accredited care centers; experts in COPD and related lung diseases; relevant subject matter experts, including primary care physicians; clinical trial designers; health economists and psychosocial experts, all working together to devise creative ways to support patients and their families in every aspect of their lives. COPD360Net is governed by a steering committee that includes clinical lead experts from participating centers, key content specialists and both patient and caregiver representatives.

#### **Forward-Looking Statements**

*This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the timing of initiation, completion and reporting of results of clinical studies, and our anticipated regulatory filings, strategy, business plans and focus. The use of words such as "may," "might," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "project," "intend," "future," "potential," or "continue," and other similar expressions are intended to identify such forward-looking statements. All such forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include fluctuations in our stock price, changes in market conditions and satisfaction of customary closing conditions related to the public offering and those risks more fully discussed in the section entitled "Risk Factors" in Kaleido's annual report on Form 10-K for the fiscal year ended December 31, 2020, which is available at [www.sec.gov](http://www.sec.gov), as well as discussions of potential risks, uncertainties, and other important factors in Kaleido's subsequent filings with the Securities and Exchange Commission. Any forward-looking statements represent Kaleido's views only as of today and should not be relied upon as representing its views as of any subsequent date. All information in this press release is as of the date of the release, and Kaleido undertakes no duty to update this information unless required by law.*

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