# Kaleido Biosciences Reports Positive Results from Non-IND Study Demonstrating a Reduction in COVID-19 Related Healthcare Utilization and Recovery Time in Patients with Mild-to-Moderate COVID-19 and One or More Comorbidity

March 24, 2021

***KB109 demonstrated favorable safety and tolerability profile***

***Kaleido intends to file an Investigational New Drug (IND) application, with the goal of advancing KB109 directly into a pivotal registration program***

***Company to host conference call today at 8:30am ET***

LEXINGTON, Mass., March 24, 2021 (GLOBE NEWSWIRE) -- Kaleido Biosciences, Inc. (Nasdaq: KLDO) today reported positive results from a non-IND study of KB109 in patients with mild-to-moderate COVID-19. An analysis from the full dataset demonstrated a reduction in overall COVID-19 related healthcare utilization—comprised of hospitalizations, emergency room visits, and urgent care visits. The study also demonstrated a significant reduction in recovery time for patients age 45 and older or with one or more comorbidity who received KB109 plus self-supportive care as compared to patients receiving self-supportive care alone. The study was a multi-center, open label, controlled clinical study of 350 patients in which 181 received KB109 plus self-supportive care and 169 received self-supportive care alone. KB109 is a novel, orally administered product candidate based on the Company's Microbiome Metabolic Therapy (MMT™) platform.

**Summary of Results**

- Primary Endpoint: KB109 demonstrated an overall favorable safety and tolerability profile with no unexpected treatment-related adverse events.
- KB109 reduced healthcare utilization, as measured by the total number of hospitalizations, emergency room visits, and urgent care visits by approximately 62 percent among patients with one or more comorbidity and by approximately 51 percent overall.
- KB109 showed the greatest impact for patients with one or more underlying comorbidity, who have a considerably longer disease course.
- For patients with one or more comorbidity, KB109 reduced median time to resolution of the 13 overall COVID-19 symptoms from 30 to 21 days (HR=1.422 [95% CI: 0.898, 2.250]; p=NS).
- In an exploratory analysis of patients ages 45 and older or with one or more comorbidity, KB109 significantly reduced median time to resolution of the 13 overall COVID-19 symptoms from 31 to 21 days (HR=1.597 [95% CI: 1.064, 2.398]; p<0.05).
- KB109 targets the host immune system rather than the virus and is therefore likely to demonstrate similar results against emerging virus variants, though this has not yet been studied in an IND trial.

"Despite historic progress in advancing COVID-19 vaccinations, new strains of the virus continue to emerge, necessitating safe, orally available therapies for patients around the world," said Dan Menichella, President, and Chief Executive Officer of Kaleido Biosciences. "Based on these results, we are excited to advance KB109—which can be administered at home—into an IND to assess whether it may help improve patient outcomes, particularly among more vulnerable populations."

Continued Mr. Menichella: "Because KB109 is designed to affect the host's immune response, rather than the virus itself, we believe it may produce a similar response to virus variants or other types of viral respiratory infections. With the goal of moving into a pivotal registration program in mild-to-moderate COVID-19 patients who are at risk for prolonged symptoms, we look forward to filing an IND application with the FDA and a Clinical Trials Application with other regulatory agencies."

As a non-interventional extension to the completed study, Kaleido is continuing to study the impact of KB109 on the incidence of 'Long-COVID'—an emerging concern where symptoms of the virus persist in patients for weeks and months.

"The data released today from Kaleido Biosciences are highly impressive and I believe represent an exceptional advance," commented John P. Haran, M.D., Ph.D., Associate Professor of Emergency Medicine, Microbiology & Physiological Systems and clinical director of the UMass Center for Microbiome Research at the University of Massachusetts Medical School. "Oral therapies that reduce the duration of symptoms in patients with COVID-19 are in great need and would offer much needed therapeutics to patients suffering from the long-lasting effects after infection. If these data are replicated in a pivotal drug study, they would represent an opportunity for an oral therapeutic targeting the microbiome, the trillions of microbes living inside our bodies, to reduce healthcare utilization and accelerate patient recovery from COVID-19."

The mechanism of KB109's induction of short-chain fatty acid production is validated in multiple preclinical studies across both viral and bacterial respiratory pathogens, offering the potential to provide an intervention for a variety of viral respiratory infections.

**Conference Call and Webcast Details**
The Company will host a conference call today at 8:30am ET to discuss the data. To access the call, please dial 833-423-0448 (domestic) or 956-394-3566 (international) with conference ID 1176787. The webcast, and accompanying slide presentation, can be accessed through the

"Investors" section of Kaleido's website at www.kaleido.com.

**About the Potential Role of the Microbiome in COVID-19**
COVID-19 infection has been associated with activation of an inappropriate inflammatory cascade, which in some patients can cause an abnormally aggressive immune response that can lead to pneumonia and respiratory failure. Metabolites such as short chain fatty acids (SCFAs) produced by the microbiome through utilization of glycans are modulators of the immune response and therefore could play a role in limiting this inflammatory cascade.

In preclinical models, increased SFCAs and/or SFCA-producing taxa, have been shown to influence immune pathways, mitigate immune pathology, and improve survival and morbidity associated with severe respiratory viral infections.[1,2] Commensal microbiota composition critically regulates the generation of virus-specific CD4 and CD8 T cells and antibody responses following respiratory influenza virus infection.[3]

Human data also support the role of SCFAs in reducing the impact of viral infections. In patients undergoing hematopoietic stem cell transplants who have contracted respiratory viral infections, including coronavirus, the presence of SCFA-producing taxa has been associated with a significantly reduced risk of progression to lower respiratory tract infections, which can have substantial morbidity in this patient population.[4] KB109 is Generally Recognized as Safe (GRAS) for its intended use and was selected for evaluation in these COVID-19 clinical studies based on its demonstrated ability to increase production of SCFAs as well as to promote commensal bacteria and reduce pathogenic bacteria *ex vivo*.

**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/.

**Forward-Looking Statements**
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding the therapeutic potential of our MMT candidates, regulatory interactions and plans, and our strategy, business plans and focus. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, those related to the breadth of our pipeline of product candidates, the strength of our proprietary product platform, the efficiency of our discovery and development approach, the clinical development and safety profile of our MMT candidates and their therapeutic potential, whether and when, if at all, regulatory agencies will approve our IND application or clinical trial applications for KB109, whether and when, if at all, our MMT candidates will receive approval from the U.S. Food and Drug Administration or other regulatory agencies and for which, if any, indications, competition from other biotechnology companies, and other risks identified in our SEC filings, including our most recent Form 10-K, and subsequent filings with the SEC. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. We disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

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1. Antunes, K.H., et al. Microbiota-derived acetate protects against respiratory syncytial virus infection through a GPR43-type 1 interferon response. Nat Commun. 2019, 10, 3273.
2. Trompette, A., et al. Dietary Fiber Confers Protection against Flu by Shaping Ly6c- Patrolling Monocyte Hematopoiesis and CD8+ T Cell Metabolism. Immunity. 2018, May 15;48(5):992-1005.e8.
3. Ichinohe, T., et. al. Microbiota regulates immune defense against respiratory tract influenza A virus infection. Proceedings of the National Academy of Sciences. Mar 2011, 108 (13) 5354-5359.
4. Haak, B.W., et al. Impact of gut colonization with butyrate-producing microbiota on respiratory viral infection following allo-HCT. Blood. 2018. 131, 2978-2986.


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