Kaleido Biosciences Initiates Controlled Clinical Study with Massachusetts General Hospital of Microbiome Metabolic Therapy KB109 in Outpatients with Mild-to-Moderate COVID-19

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- Second Study Launched in Kaleido's COVID-19 Clinical Development Program for this Rapidly Growing Patient Population -

LEXINGTON, Mass., July 23, 2020 (GLOBE NEWSWIRE) -- Kaleido Biosciences, Inc. (Nasdaq: KLDO), a clinical-stage healthcare company with a chemistry-driven approach to targeting the microbiome to treat disease and improve human health, today announced the initiation of a controlled clinical study (K032) being conducted with Massachusetts General Hospital, evaluating Microbiome Metabolic Therapy (MMT) candidate KB109 added to Supportive Self-Care (SSC) for outpatients with mild-to-moderate COVID-19. This is the second clinical study Kaleido has initiated in this patient population, which, according to the World Health Organization, comprises approximately 80% of those experiencing symptoms.

"Massachusetts General Hospital is an ideal partner to conduct this important clinical study, building on the previously initiated study and adding to the scientific rationale for the role of the microbiome in the immune response to respiratory viral infections," said Katharine Knobil, M.D., Kaleido's Chief Medical Officer and Head of Research & Development. "As the spread of the virus continues, further study is needed in patients with mild-to-moderate disease to understand how to prevent progression to more severe sequelae. The evidence supporting the role of the microbiome in viral infections is compelling, and our clinical program will evaluate the effects of KB109 in mitigating inappropriate inflammatory response to COVID-19, and potentially avoiding more serious complications."

"This study has the potential to inform us about how targeting the microbiome may help modulate the immune pathology associated with COVID-19 in the largest segment of infected patients, where there is still a significant need and opportunity," said Michael Dougan, M.D., Ph.D., of the Division of Gastroenterology, Massachusetts General Hospital and Assistant Professor, Harvard Medical School.

This non-IND clinical study (K032) aims to include approximately 50 COVID-19 positive outpatients with mild-to-moderate disease. Patients will be randomized (1:1) to either receive SSC (the control group) or SSC plus KB109 for two weeks, and then followed for three weeks. Patients will be evaluated for safety, physiologic effects, and gut microbiota structure and function.

Patients will monitor and record objective measures, such as temperature and oxygen levels, and participate in telemedicine visits with clinicians. The study will assess healthcare utilization, and biomarkers of the inflammatory response that will inform the potential of KB109 in COVID-19 as well as other viral and bacterial infections. The composition and metabolites of patients' microbiomes will be evaluated to understand the link between changes in the microbiome and inflammatory response to COVID-19 infection.

This study is part of Kaleido's clinical development program in COVID-19. The Company recently initiated a separate multi-center study (K031; NCT identifier NCT04414124) of KB109 with similar assessments and aims to enroll approximately 350 outpatients with mild-to-moderate COVID-19. Top-line data from the ongoing multicenter study (K031) are expected in the fourth quarter of 2020 and top-line data from this study with Massachusetts General Hospital (K032) are expected in the first quarter of 2021.

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. Scientific evidence indicates that metabolites such as short chain fatty acids (SCFAs) produced by the microbiome through fermentation of glycans, are modulators of the immune response and therefore could potentially 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]

In-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) 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, the timing of initiation, completion and reporting of results of clinical studies, 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, our MMT candidates will receive approval form the U.S. Food and Drug Administration 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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