Kaleido Biosciences Announces Presentation of Clinical Study and Ex Vivo Data Supporting the Development of Novel Microbiome Metabolic Therapies for Hyperammonemia at The International Liver Congress™ 2019 (EASL)

April 12, 2019

LEXINGTON, Mass., April 12, 2019 (GLOBE NEWSWIRE) -- Kaleido Biosciences, Inc. (Nasdaq: KLDO), a clinical-stage healthcare company with a differentiated, chemistry-driven approach to leveraging the potential of the microbiome organ to treat disease and improve human health, today presented clinical study and *ex vivo* data supporting its Microbiome Metabolic Therapy (MMT™) programs in diseases resulting in hyperammonemia at The International Liver Congress™ 2019, the Annual Meeting of the European Association for the Study of Liver (EASL).

The gut microbiome plays a significant role in the production and consumption of ammonia, which is central to the pathogenesis of several ammonia processing-related diseases. Kaleido is currently advancing novel MMT product candidates, KB195 and KB174, targeted at reducing net ammonia production by modulating the metabolic output and profile of the microbiome.

"These data demonstrate the potential of our MMTs to reduce ammonia produced by the gut microbiome and support the development of lead candidates for the treatment of diseases resulting in hyperammonemia," said Katharine Knobil, M.D., Chief Medical Officer and Head of Research & Development at Kaleido. "We are currently evaluating our MMT candidates in two non-IND clinical studies in patients with cirrhosis and urea cycle disorders, and we expect results later this year."

In an *ex vivo* screening of more than 300 compounds across healthy human microbiome samples, KB195 showed a significant effect on ammonia reduction. In *ex vivo* testing, KB195 reduced ammonia levels in 95 percent (18/19) of microbiome samples from patients with hepatic impairment. In 74 percent (14/19) of the samples, KB195 also resulted in a greater reduction in ammonia than lactulose, an approved treatment for hepatic encephalopathy.

The safety and tolerability of KB195 and its effect on microbiome nitrogen metabolism were subsequently evaluated in a randomized, controlled, double-blind, non-Investigational New Drug (non-IND) clinical study in healthy human subjects. The study enrolled 47 subjects, who were administered a high-protein diet and randomized to receive either KB195, a comparator glycan, or negative control, and the dose was escalated during the study. A lactose-^{15}N-ureide tracer was used to evaluate changes in nitrogen metabolism in the gut; a reduction of this tracer in the urine is consistent with a reduction in net ammonia production by the gut microbiome. The KB195 group had a significant decrease (40.5 percent) in urinary ^{15}N excretion compared to negative control (p=0.0126) at a dose of 36g twice daily (72g/day), independent of starting microbiome composition.

Overall, there were no safety signals following KB195 treatment. Most treatment-emergent adverse events (TEAEs) during the study were mild in severity. Of the two subjects who reported moderate TEAEs, none were deemed related to KB195. Tolerability was evaluated using the Gastrointestinal Tolerability Questionnaire (GITQ), which assesses symptoms like flatulence and abdominal cramping, and the Bristol Stool Scale (BSS), which assesses stool consistency. KB195 was well tolerated and comparable to the negative control at all doses in both the GITQ and BSS. Treatment with KB195 also resulted in fewer subjects reporting diarrhea than with the comparator glycan.

Kaleido has received IND clearance from the U.S. Food and Drug Administration to initiate a Phase 2 clinical trial of KB195 in patients with urea cycle disorders and expects enrollment to begin during the first half of 2019. In its hepatic encephalopathy program, the Company is evaluating KB174 in a non-IND clinical study in patients with cirrhosis.

The poster, "Identification of Novel Glycans That Target Gut Microbiota-Associated Ammonia Production", was presented in a poster session today and will be available on Kaleido's website at https://kaleido.com/platform/#publications.

About Kaleido Biosciences

Kaleido Biosciences is a clinical-stage healthcare company with a differentiated, chemistry-driven approach to leveraging the potential of the microbiome organ to treat disease and improve human health. The Company has built a human-centric 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 organ'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 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 non-IND clinical study for KB195 in patients with UCD, non-IND clinical study for KB174 in patients with cirrhosis as well as non-IND clinical study of KB174 in healthy volunteers to study dosing, including statements regarding the timing for receipt of data from such studies and potential future studies, 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 final prospectus for our initial public offering, 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. Any forward-looking statements contained in this press release represent our views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

Contact

Amy Reilly
617-890-5721
amy.reilly@kaleido.com

Source: Kaleido Biosciences