



Progenity Presents Data at ACG 2019

October 29, 2019

Highlighting Opportunities for Technologies Aimed at Improving Diagnosis and Treatment of Gastrointestinal Disorders

SAN DIEGO, October 29, 2019 – Progenity, Inc., a privately held biotechnology company, presented three posters this week at the 2019 American College of Gastroenterology Annual Scientific Meeting in San Antonio, Texas. The company presented data on a study that demonstrates the potential for improved efficacy in treating inflammatory bowel disease (IBD) when targeted biologics are applied directly at the disease site. Progenity also presented results from two meta-analyses that highlight the need for new methods for diagnosing small intestinal bacterial overgrowth (SIBO).

“Current methods for sampling the gut make it difficult for healthcare providers to accurately diagnose and monitor gastrointestinal disorders. Even after diagnosis, drug therapy presents a number of challenges, including achieving the most effective therapeutic dose at the site of disease,” said Harry Stylli, PhD, chief executive officer, chairman of the board, and co-founder of Progenity. “At Progenity, our Precision Medicine team is working to develop diagnostic and therapeutic technology platforms, spearheaded by ingestible devices and supported by a broad and growing intellectual property portfolio, that will address these challenges, including tests for SIBO, nonalcoholic steatohepatitis (NASH), colon cancer, and inflammatory bowel disease (IBD). This latest research represents early steps toward our novel diagnostic and drug therapy approach that we believe could prove transformative for GI medicine.”

In the targeted IBD therapeutics research poster, Progenity assessed the efficacy of direct application versus systemic administration of anti- $\alpha 4\beta 7$ integrin antibodies, an approved treatment for IBD, in a mouse model. The data showed that when anti- $\alpha 4\beta 7$ integrin antibodies were directly delivered to the lining of the gut, drug concentrations were increased in colon contents and tissues but remained low in the blood. Drug levels also remained elevated in target tissues longer than those observed in systemic circulation. Additionally, the presence of T-cells responsible for inflammation were significantly reduced in number compared to systemic administration. Ultimately, results of the study show a potential increase in efficacy when drugs are directly delivered to the lining of the gut.

“Direct administration of drug therapies via ingestible technologies shows tremendous promise to improve treatment outcomes in patients with gastrointestinal diseases,” said William Sandborn, MD, chief of gastroenterology and director of the Inflammatory Bowel Disease Center at UC San Diego Health, and one of the study’s authors. “Administering a high therapeutic dose directly to the site of disease with a noninvasive method of delivery could be key to increasing treatment efficacy for these burdensome disorders.”

Progenity’s two meta-analysis studies examined the consistency and reliability of two current methods for diagnosing SIBO in patients: assessment of bacterial colony forming units (CFU) in endoscopic samples, and glucose breath testing. SIBO is a clinical condition associated with abnormally high bacterial counts in the small intestine and clinical symptoms such as diarrhea, constipation, abdominal pain, distension and bloating.

- For studies examining CFUs in endoscopic samples, Progenity found it difficult to determine test reliability or consistency with results due to variability in sampling regions, contamination, difficulty culturing and counting bacteria, and lack of standardization in procedures and reproducibility.
- For glucose breath testing, the meta analysis showed moderate to poor agreement between the breath test and endoscopy aspirate culture, which could be due to the heterogeneity found between study design and implementation of breath tests, as well as lack of standardization for endoscopy aspirate culture protocols.

These meta analyses suggest that better tools and standardization of processes are needed for evaluating patients with suspected SIBO.

Progenity is developing an ingestible diagnostic platform with onboard assays to aid in the diagnosis of numerous GI disorders. This platform technology has the potential to become the gold standard for noninvasive evaluation of the intestinal milieu, enabling a more personalized approach to patient management.

Presentation details are below:

Characterization of the bacterial makeup and quantitative distribution in patients with suspected small intestine bacterial overgrowth (SIBO): A meta-analysis

Presenter: Shaoying Nikki Lee, PhD
October 27, 3:30 PM – 7:00 PM Central
Poster: P0797

Accuracy of glucose breath testing for small intestine bacterial overgrowth (SIBO) using endoscopy aspirate cultures as a reference standard: A meta-analysis

Presenter: Shaoying Nikki Lee, PhD
October 27, at 3:30 PM – 7:00 PM Central
Poster: P0796

Targeted topical anti- $\alpha 4\beta 7$ integrin antibody results in reduced accumulation of $\alpha 4\beta 7$ memory T-cells in gut tissue in DSS-induced colitis mice

Presenter: Mitchell L. Jones, MD, PhD
October 29, at 10:30 AM – 4:00 PM Central
Poster: P2336

To download the posters and learn more about Progenity's precision medicine platforms, please see our [research page](#).