Progenity Presents Proof-of-Concept Data on Proprietary Ingestible Technologies for Gastrointestinal Disorders

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We announced results from three studies that represent potential breakthrough systems for diagnosing, treating, and monitoring digestive diseases through ingestible technologies.

SAN DIEGO—May 22, 2019—Progenity, Inc., a privately held biotechnology company developing proprietary precision medicine solutions across genomic/epigenomic, proteomic, and microbiomic diagnostic and therapeutic platforms, this week announced results from three studies that represent potential breakthrough systems for diagnosing, treating, and monitoring digestive diseases through ingestible technologies.

Proof-of-concept studies in both human and pre-clinical models showed Progenity's ingestible diagnostic capsule platform is capable of autonomous location-based sampling, biomolecular analysis, and real-time wireless communications for assessing and monitoring gastrointestinal health. Further, data from two preclinical proof-of-concept studies looking at direct topical delivery of monoclonal antibodies (mAbs) to the lining of the gut versus systemic administration with an injection, demonstrate in pre-clinical models the potential for improved efficacy and safety in the treatment of inflammatory bowel disease (IBD). The data from these studies were presented at Digestive Disease Week 2019 in San Diego, California, May 18–21.

"In our continued efforts to make healthcare more precise and personal, we are developing potentially the first platform technology capable of functioning as an ingestible digital fluorometric laboratory with a range of possible assays for gastrointestinal, metabolic, and microbial disorders," said Harry Stylli, CEO, Chairman of the Board and a founder of Progenity.

"These platform technologies are intended to directly address challenges clinicians face in diagnosing gastrointestinal disorders and treating patients with therapies that can result in low response rates and high toxicity. Our proof-of-concept studies demonstrate great promise that these technologies can be used in a variety of applications to greatly improve the ability of clinicians to diagnose, treat, and monitor digestive diseases. Progenity is also developing and manufacturing its own pipeline of drugs with established efficacy and safety profiles in IBD. We believe our proprietary platform will help improve the therapeutic safety and efficacy of currently available therapies and their combinations for the treatment of IBD and other diseases," stated Stylli.

Development of an Ingestible Diagnostic Capsule to Monitor Gastrointestinal Health
Progenity presented results of a study evaluating the function of a system that includes an autonomous, swallowable diagnostic capsule for in situ biomolecular detection. As a proof of concept, this system has been designed to aid in the diagnosis and monitoring of small intestinal bacterial overgrowth (SIBO). The system has three components: a capsule, a wearable receiver, and analysis software. The capsule is a single-use device swallowed by the patient. The capsule determines its location in the digestive tract, collects a sample, and performs an onboard assay to measure bacterial load. The results of the assay are wirelessly communicated from the wearable receiver to the software for review by the healthcare provider.

SIBO is a clinical condition associated with abnormally high bacterial counts in the small intestine and symptoms such as diarrhea, constipation, abdominal pain, distension and bloating. SIBO is under-diagnosed and significant limitations exist with currently available diagnostic testing methods. Aspiration and culture of proximal jejunal contents is invasive, costly, and has low reproducibility. Breath testing is noninvasive but has poor sensitivity and specificity and lacks standardization of methodology. As a result, patients with SIBO are poorly served. Progenity's diagnostic capsule system represents the potential for a powerful new tool to aid in the diagnosis of SIBO, with the sensitivity and reproducibility of the aspirate and culture method combined with the noninvasive nature of breath testing.

The system has undergone a series of validation and verification tests including full Clinical Laboratory Standards Institute (CLSI) verification of the assay and a clinical evaluation of the localization algorithm. The assay and call algorithm continue to be evaluated ex vivo in an ongoing prospective human clinical trial.

Direct Topical Delivery of Monoclonal Antibodies Could Improve Treatment of IBD
Inflammatory bowel disease (IBD) is characterized by a disproportionate inflammatory response in gastrointestinal tissues, leading to damage and clinical symptoms. There is an urgent need to achieve higher rates of clinical response, remission, and mucosal healing in IBD. Several therapeutic monoclonal antibodies (mAbs) have revolutionized the treatment of these disorders, but despite their potency, have provided limited long-term efficacy in patients due to lack of response and chronic complication.

Two posters presented by Progenity hypothesize that improved response can be achieved via direct topical delivery of mAbs to the site of disease by providing concentrations sufficient to drive improved efficacy while reducing the systemic toxicity that is often associated with these agents when administered systemically. The posters describe results from comparative studies in which mouse models of induced chronic colitis were administered mAbs with either a systemic injection into the body cavity (intraperitoneal – IP) or direct topical application to the lining of the large intestine through a surgical portal (intracecal – IC). Results showed direct topical (IC) administration was more efficacious when compared to systemic (IP) delivery of anti-TNFα antibody and anti-∝4β7 antibody in mouse models of acute colitis. Taken together, these findings provide a proof of concept for direct topical delivery of therapeutic antibodies and suggest the potential for improved efficacy in the treatment of IBD.

For more information about these studies, visit our Clinical Research page.