Progenity Initiates Safety and Tolerability Study of its Smart Capsule-Based Oral Drug Delivery System for GI Diseases

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SAN DIEGO, Feb. 17, 2021 (GLOBE NEWSWIRE) -- Progenity, Inc. (Nasdaq: PROG), a biotechnology company with an established track record of success developing and commercializing molecular testing products, today announced the initiation of a clinical study for their Drug Delivery System (DDS) capsule, an ingestible and self-guided drug delivery device. The study will evaluate the capsule's safety and tolerability in the gastrointestinal (GI) tract of Normal Healthy Volunteers (NHV). The study will also collect the first clinical data on the ability of the DDS to auto-locate and accurately deliver a payload to the colon, a key delivery site for the treatment of ulcerative colitis.

This study will investigate the *in vivo* behavior of the DDS using the well-established method of scintigraphic characterization. Gamma scintigraphy will be used to validate the DDS GI localization as well as the drug delivery accuracy using a saline solution payload that includes radioisotopes. The DDS capsule will be evaluated in a single-dose application to approximately 12 subjects in three separate dosing cohorts. Results of the study are expected in the second quarter of this year.

"This research is a significant step in our efforts toward improving the management of ulcerative colitis, where therapy is often challenged by the inability to achieve sufficient drug concentrations at the site of disease without incurring dose-limiting side effects," said William Sandborn MD, Chief of the Division of Gastroenterology and Director of the Inflammatory Bowel Disease Center at the University of California San Diego. "Verifying the safety and tolerability of this drug delivery system will allow us to advance this technology to potentially provide a noninvasive, oral solution for safe and effective treatment of this and other GI diseases."

Progenity designed the DDS capsule with the aim of ultimately using it to deliver bolus doses of therapeutic compounds formulated in proprietary solutions at a defined location within the GI tract. If successful, the DDS could be used to transport previously approved therapeutics directly to their intended disease target in the GI tract, thereby improving efficacy through increased localized drug concentration while potentially minimizing harmful side effects associated with systemic drug delivery. This technology offers the potential to improve treatment for patients suffering from conditions such as ulcerative colitis (UC) and inflammatory bowel disease (IBD). Current drug treatments for these conditions suffer from less than optimal efficacies at safe doses, leading to a loss of response in the majority of patients within the first few years of treatment.

Progenity has two lead drug-device candidates utilizing the DDS technology: PGN-001, a high-concentration, liquid formulation of adalimumab, and PGN-600 a liquid formulation of tofacitinib. Both are under development for the treatment of ulcerative colitis. Using intracecal catheter preclinical colitis models, the company previously observed significant efficacy, as well as both high local tissue drug levels with localized drug delivery and reduced systemic drug exposure, compared to systemic injection.

For more information about Progenity's products and pipeline visit www.progenity.com, or follow the company on LinkedIn or Twitter.

About Progenity
Progenity, Inc. is a biotechnology company with an established track record of success in developing and commercializing molecular testing products, as well as innovating in the field of precision medicine. Progenity provides *in vitro* molecular tests designed to improve lives by providing actionable information that helps guide patients and physicians in making medical decisions during key life stages. The company applies a multi-omics approach, combining genomics, epigenomics, proteomics, and metabolomics to its molecular testing products and to the development of a suite of investigational ingestible devices designed to provide precise diagnostic sampling and drug delivery solutions. Progenity's vision is to transform healthcare to become more precise and personal by improving diagnoses of disease and improving patient outcomes through localized treatment with targeted therapies. For additional information about Progenity, please visit the company's website at www.progenity.com.

Forward Looking Statements
This press release contains "forward-looking statements," which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements, other than statements of historical facts included in this press release, including statements regarding the development progress of our Drug Delivery System (DDS) capsule, its future use in managing ulcerative colitis, and the performance of the Drug Delivery System (DDS) capsule in an upcoming clinical study. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that could cause the Company's actual results to differ materially from the forward-looking statements expressed or implied in this press release, including the ongoing COVID-19 pandemic and associated shelter-in-place orders, our ability to develop and commercialize our testing products, the performance of third parties in connection with the commercialization and development of our products, regulatory developments in the United States and foreign countries, our ability to obtain and maintain regulatory approval or clearance of our products on expected timelines or at all, our ability to improve and enhance our products, our plans to research, develop, and commercialize new products, the development, regulatory approval, efficacy, and commercialization of competing products, the loss or retirement of key scientific or management personnel, and those risks described in "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, filed with the SEC on November 11, 2020, and other subsequent documents we file with the SEC. We claim the protection of the Safe Harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. We expressly disclaim any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

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