Progenity Progresses its Drug Delivery System Clinical Device Performance Studies

March 10, 2022

Clinical Device Performance Study in Healthy Volunteers Demonstrated Accurate Localization and Delivery

A Clinical Device Performance Study in Patients with Ulcerative Colitis is Now Recruiting

SAN DIEGO, March 10, 2022 (GLOBE NEWSWIRE) -- Progenity, Inc. (Nasdaq: PROG), an innovative biotechnology company, today announced progress with its clinical device performance study plan, evaluating the device function and safety of its Drug Delivery System (DDS) capsule.

Progenity's first clinical device performance study evaluated the safety and tolerability of its DDS capsule and validation of the device's localization and delivery function in healthy volunteers. The DDS capsule was ingested orally and after localization, it released a saline solution payload that included radioisotopes. Scintigraphic imaging was used to indicate device localization and payload delivery to the lower GI tract. The DDS capsule was well tolerated and the study demonstrated the ability to accurately identify entry into the colon in 10 out of 12 subjects, trigger release of a liquid payload, and achieve pan-colon distribution with no devices deploying before entering the colon.

"Having completed a successful study in healthy volunteers, we are now recruiting patients with active ulcerative colitis to continue evaluating the performance of our clinical device," said Adi Mohanty, Chief Executive Officer of Progenity. "These studies are important steps toward our goal of initiating a therapeutic intervention trial for our PGN-600 program to evaluate delivery of therapeutics directly to the site of disease in patients suffering from ulcerative colitis, and if we are able to establish accurate delivery in ulcerative colitis, the platform should also be applicable for localized delivery of other drugs."

The follow-on study design will mirror that of the first study, evaluating the delivery of an imaging agent to the colon using the DDS device, and will be conducted in patients with active ulcerative colitis. This in-patient study will be conducted at the Scintipharma research unit in Lexington, Kentucky. Enrollment is open to patients 18-75 years old with active ulcerative colitis. People who are interested in participating can send a message to clinical.trials@progenity.com to obtain information about the study.

About the Drug Delivery System (DDS) and PGN-600
Progenity's Drug Delivery System (DDS) is an ingestible capsule designed for targeted delivery of therapeutics to improve treatment of inflammatory bowel disease (IBD). For the 1.8 million patients in the United States who suffer from IBD, existing therapeutics offer less than ideal efficacy, likely because of the challenges with safely achieving sufficient drug levels in the affected tissues.

The DDS targeted therapeutics platform utilizes a novel approach that could improve IBD patient outcomes by maximizing the available dose at the site of disease while reducing systemic toxicity. Once swallowed, the capsule is designed to autonomously identify when it has arrived at a specific location in the gastrointestinal tract and release a therapeutic dose at the site of disease. The DDS is approximately the size of a "000" capsule, the size of many fish oil capsules. It is designed to deliver a range of liquid formulations in amounts up to 500 µL. In normal healthy volunteers, the DDS was shown to be safe and accurate in identifying entry into the colon. Progenity is a recipient of the Crohn's and Colitis Foundation IBD Ventures development grant to, in part, support development and further clinical evaluation of the DDS platform, which aims to improve the quality of life for patients with inflammatory bowel disease.

Progenity is developing the PGN-600 program, which consists of a liquid formulation of tofacitinib delivered to the colon via the DDS capsule, for the treatment of ulcerative colitis. The company has shown preclinically in canines that successful targeted delivery using PGN-600 can lead to reduced drug levels in blood and increased drug levels in tissue at least 25 times higher along the length of the colon as compared to the equivalent standard oral dose. Progenity expects to initiate a phase 1 safety clinical trial of PGN-600 in late 2022.

About Progenity
Progenity, Inc. is a biotechnology company innovating in the fields of gastrointestinal health, oral biotherapeutics, and women's health. Progenity 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 more information visit www.progenity.com, or follow the company on LinkedIn or Twitter.

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 are forward-looking statements. Forward-looking statements include statements regarding Progenity's products under development and the potential uses for such products in the United States and globally. 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," "develop," "plan" or the negative of these terms, and similar expressions, or statements regarding intent, belief, or current expectations, are forward looking statements. These statements involve known and unknown risks, uncertainties and other factors that could cause Progenity's actual results to differ materially from the forward-looking statements expressed or implied in this press release, including Progenity's ability to successfully develop and commercialize its products under development, the uncertainties inherent in the development process, such as the regulatory approval process, the timing of regulatory filings, the ability to identify potential partners and other matters, including the ongoing COVID-19 pandemic, that could affect sufficiency of existing cash, cash equivalents and

short-term investments to fund operations and the availability or commercial potential of Progenity's products, and those risks described in "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Progenity's Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 18, 2021, and other subsequent documents we file with the SEC, including but not limited to Progenity's Quarterly Reports on Form 10-Q. Progenity claims the protection of the Safe Harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. Progenity expressly disclaims any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

Investor Contact
Chuck Padala
Managing Director, LifeSci Advisors
ir@progenity.com
(917) 741-7792

Media Contact
Kristin Schaeffer
CG Life
media@progenity.com
(858) 457-2436