Progenity Announces Encouraging Preclinical Data Supporting the Potential of the Company's Oral Drug Delivery System in Targeting the Colon

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SAN DIEGO, Nov. 06, 2020 (GLOBE NEWSWIRE) -- Progenity, Inc. (Nasdaq: PROG), a biotechnology company with an established track record of success in developing and commercializing molecular testing products, is pleased to announce positive preliminary preclinical data regarding the performance of its oral drug delivery system (DDS). The DDS capsule uses a proprietary autonomous localization technology designed to identify the ileal/ileocecal region of the GI tract. Because the DDS localization technology is based on anatomy, it is designed to resist variability in physiological conditions like pH, motility and bacteria.

The study consisted of administration of a fully functional DDS device containing a mixture of acetaminophen and sulfasalazine in a canine animal model. The study endpoints were device function as determined by evaluation of the data from the recovered capsules and the pharmacokinetic (PK) results of the acetaminophen and 5-aminosalicylate drug products delivered using the DDS. When ingested orally, acetaminophen is typically absorbed rapidly along the entire length of the GI tract, while sulfasalazine is a prodrug that is metabolized by intestinal bacteria, resulting in the release of sulfapyridine and 5-aminosalicylate mainly in the large intestine where bacterial concentration is elevated. Progenity is pleased to report that all devices met the study endpoints, and the PK results suggest that drug was released in the large intestine. In addition, no adverse events were observed.

"Ulcerative colitis is poorly managed with current therapeutics, in part due to the inability to get sufficient drug concentrations at the site of disease without side effects. We believe the DDS platform and PGN-001 and PGN-600 have the potential to significantly improve patient outcomes by producing high drug concentrations locally at the site of disease to improve efficacy while limiting systemic exposure to ensure safety," 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.

Progenity has two lead drug-device candidates utilizing the DDS technology, PGN-001, a high-concentration formulation of adalimumab, and PGN-600 a liquid formulation of tofacitinib, both under development for the treatment of ulcerative colitis. The company has previously observed through intracecal catheter preclinical colitis models, which are designed to mimic the localized delivery of the DDS, both local delivery of drug product and reduction in systemic exposure when compared to injection.

"These exciting data provide pre-clinical evidence that the DDS platform performed as intended and accurately targeted the colon. The technology is also designed to allow for delivery of different formulations, enabling further evaluation of formulations designed to improve stability, colonic coverage and tissue uptake. We expect to evaluate the function of the DDS in normal healthy human volunteers in the first quarter of 2021," said Harry Stylli, PhD, CEO, chairman of the board and co-founder of Progenity.

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 more information on how Progenity is helping clinicians and patients prepare for life, please visit www.progenity.com.

Forward Looking Statements
This press release contains "forward-looking statements" within the meaning of the federal securities laws, 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 concerning the progress of our research and development efforts, expectations regarding the timing of future clinical trials, our potential impact on patient outcomes are forward-looking statements. 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. Such risks, uncertainties, and other factors include, among others, the ongoing COVID-19 pandemic and associated shelter-in-place orders, our ability to innovate in the field of precision medicine, the size and growth potential of the markets for our products, and our ability to serve those markets, the rate and degree of market acceptance and clinical utility of our products and coverage and rates of reimbursement for our 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, our expectations regarding our ability to obtain and maintain intellectual property protection for our products, as well as our ability to operate our business without infringing the intellectual property rights of others and those described in "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Progenity's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 filed with the U.S. Securities and Exchange Commission (SEC) and other subsequent documents we file with the SEC. 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. Until the final settlement agreements are approved and signed by the states, there can be no assurance that the amount we have accrued will be sufficient to cover Progenity's obligations relating to this matter. Progenity's obligations could also increase, potentially materially, depending on a number of factors including whether or not the agreement on the monetary terms with the states is finalized, whether an individual state or states opt out of the settlement prior to approval in order to pursue a separate action or resolution, the terms of the final approved agreements and the parties to the settlement. For additional information, please see Note 9. Commitments and Contingencies to Progenity's audited financial statements for the year ended December 31, 2019, in the Registration Statement, as well as "Risk Factors—Regulatory Risks Related to Our Business—If we or our commercial partners act in a manner that violates healthcare laws or otherwise engage in misconduct, we could face substantial penalties and our business operations, and financial condition could be adversely affected."

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