Progenity Provides Preliminary Results from Key Studies for its Targeted Therapeutics Program

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Studies show location accuracy and tolerability of the novel oral Drug Delivery System (DDS) and point to a materially enhanced therapeutic/safety index for PGN-600

SAN DIEGO, May 12, 2021 (GLOBE NEWSWIRE) -- Progenity, Inc. (Nasdaq: PROG), an innovative biotechnology company, today announced preliminary results, subject to final audited study reports by its contract research organization (CRO), from two key studies for the Company's Targeted Therapeutics program. The studies involved both the first functional clinical study of the Drug Delivery System (DDS), and the first preclinical study of PGN-600 (liquid tofacitinib delivered by DDS), one of the Company's drug/DDS combination products.

Progenity's Targeted Therapeutics program consists of drug device combination products that allow the delivery of high concentrations of proprietary drug formulations by a novel, orally ingestible capsule to the precise site of disease along the GI tract. The DDS capsule is designed to maximize the available dose at the site of disease and reduce systemic toxicity. The Company's two lead combination product candidates, PGN-001 (liquid adalimumab delivered by DDS) and PGN-600, are being developed with an initial priority for ulcerative colitis, part of the estimated $15 billion inflammatory bowel disease (IBD) market.

The company has completed its first clinical study of the fully autonomous DDS device in twelve healthy adults. This study evaluated the capsule's targeting, safety and tolerability within the gastrointestinal tract and collected the first clinical data on the ability of the DDS to auto-locate and accurately deliver a payload to the proximal colon, a key delivery site for the treatment of ulcerative colitis and Crohn's disease. The single administration study used the well-established method of scintigraphic characterization to validate the DDS localization and the drug delivery mechanism by using a saline solution payload that included radioisotopes. Initial analysis of the study results suggests the DDS was well tolerated and the majority of DDS devices functioned as intended and could accurately identify entry into the colon, trigger release of a liquid payload, and achieve pan-colon distribution.

"These results support the use of the DDS for the company's lead ulcerative colitis combination product candidate, and potentially for uses of the DDS with other therapeutics to create combination products targeting other GI diseases. By delivering solubilized therapeutics directly to the site of disease in the GI tract, the DDS can potentially improve efficacy through increased localized drug concentration while minimizing harmful side effects associated with systemic drug delivery," said William Sandborn MD, Professor of Medicine at the University of California San Diego.

Progenity also completed a preclinical study evaluating the safety, tolerability, and pharmacokinetic and pharmacodynamic effects of a seven-day administration of PGN-600 (liquid tofacitinib delivered by DDS) at doses of 10mg or 25mg per day, with direct comparison to a standard orally administered tofacitinib tablet at 10mg per day in 12 canines. This was the first study evaluating PGN-600 as a combination product of the company's proprietary solubilized formulation of tofacitinib delivered with the DDS. Initial analysis of the study results suggests PGN-600 was well tolerated, the DDS functioned as intended in the majority of doses, and resulted in significantly higher tofacitinib concentrations in colon tissue, while also showing much lower systemic blood concentrations than the equivalent 10mg dose delivered by standard oral tablet. Tissue levels and tissue to plasma ratios of tofacitinib levels along the length of the colon were at least 25x and 50x higher respectively with PGN-600 at 10mg and 25mg daily compared to the standard oral tablet formulation of 10mg. These results demonstrate that the proprietary liquid formulation of PGN-600 can achieve pan-colonic distribution and facilitate mucosal penetration. In addition, no evidence of tissue damage was observed by histology at either 10mg or 25mg of PGN-600. The results of this study should help inform the clinical dosing of PGN-600, with data suggesting that a dose lower than currently commercially available tofacitinib formulations may lead to significantly greater tissue drug concentrations and materially reduced systemic exposure, potentially resulting in enhanced efficacy and lower systemic side effects.

"The data from these two studies when considered together provide further evidence that local delivery of solubilized therapeutics using Progenity's proprietary liquid formulations to the site of disease is enabled by the DDS and may lead to improved pharmacokinetic and pharmacodynamic effects as compared to systemic administration," said Harry Stylli, PhD, CEO, chairman of the board and co-founder of Progenity. "This approach has the potential to enhance any compatible drug and holds promise for monoclonal biotherapeutics such as adalimumab. Given these results, we are proceeding with activities to enable clinical evaluation of both tofacitinib and adalimumab drug candidates (PGN-001 and PGN-600) with the ultimate goal of significantly improving treatment outcomes for patients suffering from ulcerative colitis and Crohn's disease."

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 about Progenity's products and pipeline 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, including statements regarding the development our DDS platform, the potential benefits of the DDS platform, and the development pipeline of therapeutic candidates that use the DDS, 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, including: whether we are able to develop any products that meet our desired target product profile and address the relevant clinical need or commercial opportunity; whether any products that we develop will prove to be effective in clinical trials or otherwise; whether we will obtain necessary regulatory authorizations, in a timely manner or at all; competition from existing products or new products; the timing of regulatory review and our ability to obtain regulatory marketing authorizations of our product candidates; clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs; the ongoing COVID-19 pandemic and associated shelter-in-place orders; 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 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. 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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