Progenity Provides Results from Key Study for Its Targeted Therapeutics Program

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Preclinical study shows therapeutic effect of locally delivered PGN-001 (adalimumab) drug substance

SAN DIEGO, May 26, 2021 (GLOBE NEWSWIRE) -- Progenity, Inc. (Nasdaq: PROG), an innovative biotechnology company, today announced results from a further study for the company's Targeted Therapeutics program. The study evaluated delivery of Progenity's PGN-001 (adalimumab) drug substance directly to the colon in a preclinical model of colitis.

Progenity's Targeted Therapeutics program consists of drug-device combination products under development that have the potential to deliver high concentrations of proprietary drug formulations via a novel, orally ingestible capsule to the precise site of disease along the gastrointestinal (GI) tract. The Drug Delivery System (DDS) capsule is designed to maximize the available dose at the site of disease to potentially improve efficacy and reduce systemic toxicity.

Progenity's lead Targeted Therapeutics product candidates, PGN-001 (liquid adalimumab delivered by DDS) and PGN-600 (liquid tofacitinib delivered by DDS), are being developed with an initial priority for ulcerative colitis, part of the estimated $15 billion inflammatory bowel disease market.

The company completed a preclinical study evaluating the tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of adalimumab liquid formulation (PGN-001 drug substance) delivered directly to the colon through local administration to the cecum in a swine model of induced colitis. PGN-001 drug substance was delivered in either single administration or daily repeat administration for three days by a surgically implanted intracecal (IC) catheter as a surrogate for direct delivery to the colon by the DDS. The study included healthy and induced colitis vehicle control groups.

The study found that adalimumab was detected in tissue along the length of the colon after IC administration. There was also a significant reduction in TNF-α, the proinflammatory cytokine target of adalimumab, at each of 24 and 48 hours following repeat IC doses when compared with the induced colitis control group that did not receive treatment. No treatment-related adverse events were observed and no measurable adalimumab was detected in the blood, in each case, for animals administered adalimumab by IC catheter.

"These results suggest targeted topical delivery of adalimumab may provide an advantage over systemic delivery by substantially reducing the TNF-α burden within the colonic tissue with little to no systemic breakthrough. These results are made even more impressive as adalimumab has significantly lower affinity for pig TNF-α compared to human. Not only does this support the potential use of PGN-001 as monotherapy but also as combination therapy given the minimal systemic levels and associated safety margin," said William Sandborn, MD, Professor of Medicine at the University of California San Diego.

This study builds upon data Progenity previously presented at Digestive Disease Week 2019 from a mouse model of colitis that used a species-appropriate TNF-α monoclonal antibody delivered by IC catheter. The 2019 study found that targeted IC delivery significantly reduced weight loss, decreased Disease Activity Index, improved histological score and reduced tissue inflammatory cytokines in mice when compared with vehicle controls. The 2021 study in swine models more closely represents human anatomy, allows for use of PGN-001 drug substance, and therefore provides more robust data for the potential effect in humans.

"These preclinical results provide further evidence that therapies delivered locally in the GI tract have the potential to transform the treatment of ulcerative colitis by maximizing the available dose at the site of disease while reducing systemic exposure to improve safety. We now have evidence that this is not just the case for small molecules but also for monoclonal antibodies. This opens the potential for additional candidates for our Targeted Therapeutics program, as well as pharmaceutical and biotech partnerships," said Harry Stylli, PhD, CEO, chairman of the board and co-founder of Progenity.

The company is currently performing a clinical study to obtain further supporting data for the local delivery of adalimumab, using administration by enema as a surrogate for delivery with the DDS. Preliminary results are expected this year and should further guide dosing as Progenity advances towards clinical evaluation of adalimumab delivered by the DDS in ulcerative colitis patients.

The Targeted Therapeutics program is further supported by additional data previously announced by Progenity:

- **Preclinical** data presented at DDW 2021 demonstrating the functionality of the Drug Delivery System capsule, in which the DDS capsule successfully identified the colonic entry and delivered drugs to the colon after oral administration in fasted animal models.
- **Preclinical** data presented at DDW 2021 indicating that targeted delivery of proprietary, soluble tofacitinib (PGN-600) to the site of inflammation has the potential to increase tissue absorption and coverage and reduce systemic toxicity.
- **Preclinical** results showing that the DDS in combination with proprietary, soluble tofacitinib (PGN-600) achieved a greater than 25-fold increase in drug delivery to colon tissue vs. equivalent orally administered dose. PGN-600 also demonstrated reduced systemic breakthrough.

- **Clinical** study results demonstrating that the DDS was able to target the colon and successfully release a liquid payload with pan-colonic distribution as observed by imaging, in normal healthy volunteers.

Progenity also recently announced funding from the Crohn's and Colitis Foundation to support the development and further clinical evaluation of the DDS.

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, the development pipeline of therapeutic candidates that use the DDS, and the development of drug device combination products, 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 preclinical and/or 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; preclinical and/or 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, including but not limited to our Quarterly Reports on Form 10-Q. 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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