Progenity Announces Several Patents Granted by USPTO, Strengthening the Company's Intellectual Property Position in Ingestible Therapeutics Technologies

October 13, 2021

SAN DIEGO, Oct. 13, 2021 (GLOBE NEWSWIRE) -- Progenity, Inc. (Nasdaq: PROG), an innovative biotechnology company, announced today that the United States Patent and Trademark Office (USPTO) has issued four patents related to its ingestible technologies for delivery of therapeutics via the gastrointestinal (GI) tract.

The USPTO has issued U.S. Patent No. 11,007,356 entitled, "Ingestible device for delivery of therapeutic agent to the gastrointestinal tract." The patent is directed to methods and devices for delivery of a therapeutic agent into gastrointestinal tissue for systemic uptake. Progenity's Oral Biotherapeutic Delivery System (OBDS), currently under development, is designed for systemic, needle-free delivery of biotherapeutics via an ingestible device. Preclinical work to date has demonstrated the ability of the OBDS to achieve bioavailability of up to 44% for proteins.

The USPTO has also issued U.S. Patent No. 11,033,490 for treatment of inflammatory conditions of the gastrointestinal tract with a Janus kinase (JAK) inhibitor. The patent covers methods of treating ulcerative colitis using an ingestible device that delivers a JAK inhibitor directly to the proximal part of the large intestine. As part of its GI-targeted therapeutics program, Progenity is preparing to initiate early clinical studies of its PGN-600 program for targeted delivery of a proprietary formulation of tofacitinib, a JAK inhibitor, to the site of disease using Progenity's Drug Delivery System (DDS), also under development. Earlier this year the company completed preclinical work with PGN-600 demonstrating at least 25 times more tofacitinib in colon tissue and less drug in blood compared to an equivalent standard oral dose.

In addition, the USPTO has issued U.S. Patent No. 11,134,889 entitled, "Treatment of a disease of the gastrointestinal tract with a SMAD7 inhibitor," and U.S. Patent No. 10,980,739 entitled, "Treatment of a disease of the gastrointestinal tract with a chemokine/chemokine receptor inhibitor." These patents are part of the company's GI-targeted therapeutics portfolio, which includes more than 170 issued patents and pending applications directed to seventeen inflammatory bowel disease targets, including TNF-alpha, IL-12/23, and integrins.

"We believe we hold one of the most robust ingestible device patent portfolios," said Eric d'Esparbes, interim CEO of Progenity. "The addition of these recent patents further strengthens our intellectual property position and underscores our commitment to innovation in advancing therapeutic discovery, development, and delivery."

The Progenity patent portfolio consists of 96 patent families, including 180 issued patents and more than 220 pending applications. The portfolio includes patents and applications directed to methods and devices for drug delivery, methods and devices for GI sampling and diagnostics, methods and compositions for treating disease, and molecular and protein tools, assays and diagnostics.

About the Oral Biotherapeutic Delivery System (OBDS)
Progenity's Oral Biotherapeutic Delivery System (OBDS) is an ingestible capsule designed for needle-free, oral delivery of large molecules, including monoclonal antibodies, peptides, and nucleic acids. These substances cannot survive stomach acids and are too large to be absorbed in the intestine and are therefore currently delivered by injection. Once swallowed, the OBDS capsule is designed to transit the intestinal tract and trigger in the small intestine, where it will use liquid jet release to inject drug directly into the small intestine for optimal bioavailability.

The OBDS platform is designed to enable delivery of liquid drug, eliminating the need for reformulation, and allows for industry-leading dosing of over 50 mg of proteins and over 5 mg of peptides. This makes the technology broadly applicable for large molecule candidates. With more frequent administration, oral delivery has the potential to improve drug efficacy and safety as compared to current injection regimens.

Progenity is currently conducting preclinical studies to demonstrate the bioavailability of its lead candidates PGN-OB1 (adalimumab, delivered by the OBDS) and PGN-OB2 (liraglutide, a GLP-1 agonist, delivered by the OBDS). In addition, the company has an agreement with Ionis Pharmaceuticals to evaluate the OBDS for delivery of antisense oligonucleotides, and it has two other agreements with leading pharmaceutical companies to evaluate delivery of their proprietary drugs via the OBDS platform.

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

The DDS promises an alternative therapeutic platform that could maximize the available dose at the site of disease while reducing systemic toxicity. Once swallowed, the DDS smart capsule is designed to autonomously identify when it has arrived at a designated location in the intestine, and release drug at the site of disease.

Progenity is currently in preclinical development of its lead candidates, PGN-001 (liquid adalimumab delivered by the DDS) and PGN-600 (liquid tofacitinib, a JAK inhibitor, delivered by the DDS) and is preparing to initiate early clinical studies in 2022. Progenity was a recipient of the Crohn's and Colitis Foundation IBD Ventures development grant in 2021 to support development and further clinical evaluation of the DDS platform.

About Progenity
Progenity, Inc. is a biotechnology company innovating in the fields of women's health, gastrointestinal health and oral biotherapeutics. 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 development of and preclinical and clinical studies evaluating the OBDS, DDS and related products under development, the estimated addressable market size for such products 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:
Robert Uhl
Managing Director, Westwicke ICR
ir@progenity.com
(619) 228-5886

Media Contact:
Kate Blom-Lowery
CG Life
media@progenity.com
(619) 743-6294