



## Progenity Announces Poster Presentations at Digestive Disease Week 2021

May 24, 2021

### Two Abstracts Support Company's Targeted Therapeutics Program including the Drug Delivery System

SAN DIEGO, May 24, 2021 (GLOBE NEWSWIRE) -- [Progenity, Inc.](#) (Nasdaq: PROG), an innovative biotechnology company, today announced the presentation of two posters related to the company's Targeted Therapeutics program presented at the 2021 [Digestive Disease Week®](#) (DDW) Virtual Event. The posters include a preclinical study evaluating treatment of intestinal inflammation with the Company's PGN-600 (liquid tofacitinib) product candidate and a second preclinical study of its investigational ingestible Drug Delivery System (DDS). DDW is the world's premier meeting for physicians, researchers, and industry in the fields of gastroenterology, hepatology, endoscopy, and gastrointestinal surgery.

"There remains a significant medical need for safe and effective targeted therapeutics to treat disorders such as ulcerative colitis and Crohn's disease. Targeted drug delivery directly to the colon has the potential to improve drug absorption at the site of inflammation, improving the efficacy of treatment," said Harry Stylli, PhD, CEO, chairman of the board and co-founder of Progenity. "These preclinical studies together suggest how, by leveraging an investigational, proprietary soluble formulation of an approved compound, such as tofacitinib, our Drug Delivery System has the potential to address the unmet need of mucosal targeted therapy for inflammatory bowel disease."

The presentation titled *Targeted Delivery of Soluble Tofacitinib Citrate to the Site of Inflammation to Improve Efficacy and Safety* studied the pharmacokinetic (PK), pharmacodynamic (PD), and biodistribution of tofacitinib liquid formulation (PGN-600) through local administration to the cecum in animal models. Tofacitinib was the first oral JAK inhibitor approved to treat moderate to severe ulcerative colitis.

Targeted local delivery of drugs directly to the colon may increase local tissue concentration to improve efficacy and lower systemic absorption. To test this, animal models were implanted with a cecal cannula to study the direct delivery of drug compared to the oral delivery of tofacitinib citrate. The study found that:

- Approximately 10- to 15-fold smaller doses of tofacitinib administered via intra-cecal delivery achieved equivalent drug concentrations with lower systemic drug exposure compared to oral delivery.
- Intra-cecal delivery of tofacitinib to the inflamed mucosa potentiated PD activity at a lower dose.
- Soluble tofacitinib formulation increased tissue absorption and coverage via intra-cecal administration.

These results indicate that targeted delivery of soluble tofacitinib to the site of inflammation increased tissue absorption and coverage, suggesting the potential to achieve greater activity with a lower risk of systemic toxicity compared to oral delivery.

In a poster presentation titled *Development of a Novel Drug Delivery System for Targeted Treatment of Ulcerative Colitis*, a preclinical proof-of-concept study was conducted to evaluate the functionality of the DDS after oral administration (PO) in fasted animal models. The DDS is an investigational ingestible electronic capsule that is designed to deliver therapeutic compounds to a defined location in the gastrointestinal tract. It is comprised of a drug reservoir containing a liquid formulation of the therapeutic compound, a removable cap, and an electronic module. In this preclinical study, two marker drugs, acetaminophen and sulfasalazine, were loaded into the capsule's drug reservoir. Acetaminophen absorption was utilized to evaluate drug release and sulfasalazine absorption was utilized to identify colon arrival.

In this study, the PK results from both drugs showed that the DDS capsule autonomously identified the colonic entry and delivered the drugs to the colon successfully. The Company believes these results support the potential of the DDS to deliver mucosal targeted therapy for GI disorders such as inflammatory bowel disease (IBD).

The study posters and findings are part of DDW's virtual sessions which can be accessed on demand until August 23, 2021. Details of the presentations are as follows:

**Presentation Title:** Targeted Delivery of Soluble Tofacitinib Citrate to the Site of Inflammation to Improve Efficacy and Safety

**Authors:** Shaoying Nikki Lee, PhD; Cheryl Stork, PhD; Chris Wahl, MD; Sharat Singh, PhD; Emil Chuang, MD

**Poster Number:** #F488

**Presentation Title:** Development of a Novel Drug Delivery System 2 (DDS2) for Colon Targeted Delivery Treatment of Ulcerative Colitis (UC)

**Authors:** Shaoying Nikki Lee, PhD; Jeff Shimizu; Cheryl Stork, PhD; Nelson Quintana; Chris Wahl, MD; Sharat Singh, PhD; Emil Chuang, MD

**Poster Number:** #Su599

The poster presentations can also be reviewed now on [the Progenity website](#).

### 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](http://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 potential for targeted drug delivery directly to the colon to improve drug absorption at the site of inflammation and improve the efficacy of treatment, the potential of the DDS to address the unmet need of mucosal targeted therapy for IBD, the potential for targeted delivery of soluble tofacitinib to the site of inflammation to achieve greater activity with a lower risk of systemic toxicity compared to oral delivery, 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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