Progenity Establishes Inflammatory Bowel Disease Clinical Advisory Board

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SAN DIEGO, June 17, 2021 (GLOBE NEWSWIRE) -- Progenity, Inc. (Nasdaq: PROG), an innovative biotechnology company, today announced the formation of its Inflammatory Bowel Disease Clinical Advisory Board. The advisory board includes respected researchers and clinicians who are thought leaders in the research and treatment of inflammatory bowel disease (IBD).

Progenity is developing a pipeline of therapeutics and diagnostics that are designed to act at the site of disease in the gastrointestinal tract with a focus on IBD. 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 IBD market.

The advisory board will provide clinical and strategic guidance on Progenity's ingestible therapeutics and diagnostics pipeline, as the company transitions from preclinical to clinical studies. Dr. William Sandborn will chair the board, which includes Dr. Geert D'Haens, Dr. Bruce Sands, and Dr. Séverine Vermeire.

"I am excited to chair the Progenity IBD clinical advisory board. The data generated by Progenity to date is compelling for the potential of therapeutics delivered locally with the DDS technology to improve efficacy and safety and enable combination therapy. I look forward to further working with Progenity on the clinical development plan for PGN-001 and PGN-600," said William Sandborn, MD, Professor of Medicine at the University of California San Diego.

The first official advisory board meeting will be held this summer to review data recently announced around the clinical performance of Progenity's drug delivery system (DDS), preclinical data for PGN-600, and initial data from an ongoing clinical study in which adalimumab is being delivered by enema as a proxy for delivery with the DDS in moderate to severe colitis patients. This data will enable the clinical advisory board to refine Progenity's clinical development plan for its lead candidates with clinical trials expected to begin in 2022.

"I am honored to join the Progenity IBD clinical advisory board. Their novel approach to the treatment of IBD has great potential and I look forward to helping guide their clinical programs. Not only do they have two promising lead candidates in PGN-001 and PGN-600, but their development platform can support not only these programs but other IBD therapeutics. Their Recoverable Sampling System allows for collection and preservation of analytes in the gastrointestinal tract which can then potentially be used to identify signatures of disease severity, predict response to therapeutic intervention and optimize dosing," said Bruce Sands MD, MS, Professor of Medicine at Icahn School of Medicine at Mount Sinai and Chief of the Division of Gastroenterology, Mount Sinai Health System.

In addition to participating in the IBD clinical advisory board, each board member will also continue in consulting roles where they help guide the strategy and development of Progenity's gastrointestinal health programs.

"We are honored to have leading minds in IBD clinical research contributing to our efforts to further study and develop our innovative pipeline," said Harry Stylli, PhD, CEO, Chairman of the Board, and co-founder of Progenity. "We believe these product candidates have the potential to improve diagnosis and treatment for the millions of patients suffering from inflammatory bowel diseases."

Short biographies for the clinical advisory board members are below, with headshots available upon request.

William Sandborn, MD
Dr. William Sandborn is Professor of Medicine at the University of California San Diego (UCSD) and is the Chief Medical Officer of Shoreline Biosciences. He completed medical school and an internal medicine residency at Loma Linda University, followed by completion of a gastroenterology fellowship at the Mayo Clinic. From 1993-2010, he was on the faculty of the Mayo Clinic, rising to Professor of Medicine, Vice Chairman of the Division of Gastroenterology and Hepatology, and Associate Dean of Research for Intellectual Property and Industry Relations. From 2011-2021 he was Professor of Medicine and Chief of the Division of Gastroenterology at the University of California San Diego (UCSD), where he continues as Professor of Medicine. Dr. Sandborn co-founded Shoreline Biosciences in 2020, co-founded Santarus in 1998 (acquired by Salix Pharmaceuticals in 2013), and was a member of the board of directors for Prometheus Biosciences from 2017-2021. Dr. Sandborn has published 849 peer-reviewed articles to date, and he was awarded the Sherman Prize for his work in inflammatory bowel disease in 2019.

Geert D'Haens, MD, PhD
Dr. Geert D'Haens is Professor of Gastroenterology at the Academic Medical Center at the University of Amsterdam, where he leads the IBD Unit. Currently, Dr. D'Haens leads a group of more than 35 IBD researchers in the AMC. He is also Medical Director of Robarts Clinical Trials in Europe and former chairman of IOIBD, the international organization for study of IBD. After graduation at the University of Leuven, Belgium, he was trained in gastroenterology, gastrointestinal endoscopy and inflammatory bowel diseases at the University Hospitals in Leuven and at the University of Chicago Hospitals under the mentorship of Paul Rutgeerts and Steven Hanauer, respectively. He completed his PhD thesis in 1996 on mechanisms causing postoperative recurrence of Crohn's disease. After that, most of his research efforts went into the mechanism of action of new IBD drugs, the development of endoscopic endpoints and surrogate markers for IBD and the effect of early intervention with anti-TNF. In 1999, he co-founded ECCO, the European Crohn's and Colitis Organization. He has authored more than 400 peer-reviewed articles so far and participates in many drug

development programs and clinical trials for IBD.

Bruce Sands, MD, MS
Dr. Bruce Sands is the Dr. Burrill B. Crohn Professor of Medicine at the Icahn School of Medicine at Mount Sinai, New York, NY. Dr. Sands was awarded his BA and MD from Boston University, and trained in internal medicine at the Hospital of the University of Pennsylvania. After completing GI fellowship at the Massachusetts General Hospital, he joined the faculty of Harvard Medical School and served as the Acting Chief of the Gastrointestinal Unit at MGH before moving to Mount Sinai in 2010 as Chief of the Dr. Henry D. Janowitz Division of Gastroenterology. Dr. Sands is widely recognized for his clinical investigations of new therapeutics for the inflammatory bowel diseases and has published over 250 original manuscripts. He was the lead investigator of the landmark studies ACCENT 2, UNIFI, and VARSITY, published in the New England Journal of Medicine.

Séverine Vermeire, MD, PhD
Dr. Séverine Vermeire is Head of the Department of Chronic Diseases & Metabolism (CHROMETA) at the KU Leuven. Since 2003, Dr. Vermeire has been a staff member at the Gastroenterology Department of the University Hospitals Leuven and was appointed Full Professor of Medicine at the KU Leuven. Dr. Vermeire obtained her MD degree and then her PhD at the KU Leuven. She further trained at the Universidad Nacional de Asuncion, Paraguay, at the Wellcome Trust Centre for Human Genetics, University of Oxford, UK, and at the Montreal General Hospital (McGill University) in Canada. She is actively involved as principal investigator in randomized clinical trials with new therapeutic compounds and has been lead investigator on several of these programs. Her scientific work resulted in more than 500 peer-reviewed articles and focuses on the role of the microbiome and genetic susceptibility in IBD and on identifying predictive signatures of treatment response. Dr. Vermeire participated in the International iCHOM consortium on development of Patient-Centered Outcomes for Inflammatory Bowel Disease. She was awarded several grants including an Advanced H2020-European Research Council (ERC) Grant (2016-2021). She served as president of the European Crohn's and Colitis Organization (ECCO) from 2014-2016 and as president of the Belgian IBD Research & Development (BIRD) Group from 2011-2013.

About Progenity
Progenity, Inc. is a biotechnology company innovating in the fields of 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. 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 clinical drug development process, such as the regulatory approval process, the timing of regulatory filings, 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.

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