Progenity Commends New Recommendations from ACOG and SMFM Supporting Non-Invasive Prenatal Testing (NIPT) for All Pregnancies

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SAN DIEGO, Aug. 21, 2020 (GLOBE NEWSWIRE) -- Progenity, Inc. (Nasdaq: PROG), a biotechnology company with an established track record of success in developing and commercializing molecular testing products including NIPT, commends the recent guideline update from the American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) recommending that all pregnant patients be offered aneuploidy screening, regardless of age or risk factors. This recommendation was featured in the new ACOG Practice Bulletin 226 – Clinical Management Guidelines for Obstetrician-Gynecologists: Screening for Fetal Chromosomal Abnormalities, which replaces Practice Bulletin 163.

"We applaud ACOG for recognizing the clinical utility of NIPT by issuing these updated clinical recommendations, which are in alignment with what the medical community has been advocating. This is a win for all pregnant patients, representing an important step toward improving access to NIPT, which the guidelines recognize as the most sensitive and specific screening tests for the common aneuploidies," said Harry Stylli, Ph.D., CEO, chairman of the board, and co-founder of Progenity.

Progenity's Innatal Prenatal Screen is a non-invasive prenatal test (NIPT) offered to women early in pregnancy to screen for risk of fetal chromosomal conditions, such as Down syndrome, trisomies 13 and 18, and sex chromosome disorders. The Innatal test offers among the highest available clinical sensitivity of >99% across all tested diseases, with validation data published as a peer-reviewed study in the Journal of Medical Screening. This test provides a low failure rate of ~1%, allowing patients to get accurate results the first time, and reducing the need for invasive follow-up testing. The Innatal test also adheres closely to medical society recommendations, including providing a patient-specific positive predictive value (PPV), as summarized by the Prenatal Information Research Consortium.

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 additional information about Progenity, please visit the company's website at www.progenity.com.

Safe Harbor Statement or Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, 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 concerning the availability of aneuploidy screening to all pregnant patients and the performance of our Innatal test 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 reflect our plans, estimates, and expectations, as of the date of this press release. These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in this press release. Such risks, uncertainties, and other factors include, among others, the ongoing COVID-19 pandemic and associated shelter-in-place orders, our ability to develop and commercialize our testing products as well as innovate in the field of precision medicine, the size and growth potential of the markets for our products, and our ability to serve those markets, the rate and degree of market acceptance and clinical utility of our products and coverage and rates of reimbursement for our products, the performance of third parties in connection with the commercialization and development of our products, including third-party suppliers for COVID-19 assays, regulatory developments in the United States and foreign countries, our ability to obtain and maintain regulatory approval or clearance of our products on expected timelines or at all, our ability to improve and enhance our products, our plans to research, develop, and commercialize new products, the development, regulatory approval, efficacy, and commercialization of competing products, the outcome of pending and future investigations and legal proceedings, the loss or retirement of key scientific or management personnel, our ability to develop and maintain our corporate infrastructure, including maintaining effective internal controls, our expectations regarding our ability to obtain and maintain intellectual property protection for our products, as well as our ability to operate our business without infringing the intellectual property rights of others, our compliance with the terms and conditions of our corporate integrity agreement, potential overpayment obligations and those risks described in "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Progenity's Registration Statement on Form S-1 (File No. 333-238738), as amended, filed with the U.S. Securities and Exchange Commission, Progenity's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, to be filed with the SEC and other subsequent documents we file with the SEC.

Progenity expressly disclaims any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by law.

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