



Progenity Presents Key Verification Study Data for Preecludia™ Preeclampsia Rule-out Test at the 2021 American College of Obstetricians and Gynecologists (ACOG) Annual Meeting

April 30, 2021

Data demonstrate strong sensitivity and negative predictive value (NPV)

SAN DIEGO, April 30, 2021 (GLOBE NEWSWIRE) -- [Progenity](#), Inc. (Nasdaq: PROG), a biotechnology company with an established track record of success in developing and commercializing molecular testing products, today announced new data from its Preecludia preeclampsia rule-out test verification study are being presented today at the 2021 ACOG Annual Meeting, with the test demonstrating sensitivity of 87.8% and a negative predictive value (NPV) of 97.0%. The company recently announced it is in the clinical validation testing phase of Preecludia, with a targeted launch expected in the second half of 2021.

Preeclampsia is the second most common cause of maternal mortality, with more than 700,000 women presenting each year with signs and symptoms of possible preeclampsia. It is characterized as a hypertensive disorder, but it is often difficult to clinically differentiate it from other hypertensive conditions in pregnancy, making diagnosis and management difficult. Ultimately, if left undiagnosed and improperly managed, preeclampsia can result in impaired organ function, seizures, stroke, and death in the mother, and may require pre-term delivery of the baby. Preeclampsia can result in both poor health outcomes and significant costs.

In the verification study being presented at ACOG today, blinded, naïve samples from twenty-four U.S. sites were tested to determine the performance of Preecludia to assess the risk of preeclampsia within fourteen days of sample collection. The samples were representative of a diverse U.S. population. Preecludia test performance, based on 303 subjects, showed 87.8% sensitivity and 97.0% NPV. These data point to the value of the test in assisting physicians to rule out patients at risk for preterm preeclampsia. By so doing, the test may provide reassurance to physicians and patients, and assist physicians in making better informed management and treatment decisions, potentially reducing overuse of interventions and resultant complications.

"These data and prior studies are strong indicators of the future performance of the Preecludia test, and we are honored to present them at ACOG," said Harry Stylli, PhD, CEO, chairman of the board and co-founder of Progenity. "They are also particularly timely as we mark Preeclampsia Awareness Month in May. We have initiated analysis of our PRO-104 validation study patient samples and plan to share the performance data, established with samples from over 1,300 patients, in the June/July timeframe. We expect to bring our Preecludia test to market soon thereafter, to finally provide doctors and expectant women with a unique, modern solution for improving preeclampsia risk assessment."

Preecludia has the potential to be the first-of-its-kind test in the United States to help healthcare providers evaluate patients who have signs and symptoms of possible preeclampsia. This laboratory developed test (LDT) is a novel multi-analyte protein biomarker assay designed to examine markers from multiple pathophysiological pathways of preeclampsia to assess risk. It is run from a simple blood draw and is designed to address the unmet need for tools to aid in the assessment and management of preeclampsia. The U.S. market opportunity for Preecludia is estimated at up to \$3 billion, with additional global market opportunities.

The data presented at ACOG are part of the virtual meeting's interactive ePosters. Details of the presentation are as follows:

Title – Performance of a novel multi-biomarker rule out preeclampsia test: a prospective verification study

Authors – Matthew Cooper, PhD, DABT, MBA; Amin Mazloom, PhD; Chelsea Obrochta, PhD(c); Ronald Wapner, MD; Todd Rosen, MD; Allan Bombard, MD

Poster number 999251

The poster presentation will also be made available on the [Progenity website](#) following the conference.

For more information about Progenity's products and pipeline visit www.progenity.com, or follow the company on [LinkedIn](#) or [Twitter](#).

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.

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 concerning the development progress of our preeclampsia rule-out test, its future use by providers to rule out preeclampsia, the performance of the rule-out test in an upcoming validation study, the completion of our upcoming validation study, and our efforts and intent to commercialize the Preecludia test and address an unmet medical need, 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 our ability to develop and commercialize our testing products, 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, 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, the fact that the data presented relates to the verification stage and may not be predicative of future results, including those from the validation stage, the development, regulatory approval, efficacy, and commercialization of competing products, the loss or retirement of key scientific or management personnel, 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, the ongoing COVID-19 pandemic and associated impact on our business, 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. 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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