New Test for Triaging Preeclampsia Passes Key Development Milestone: Progenity Releases Prospective Clinical Verification Data for its Preecludia™ Test

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High sensitivity and high negative predictive value (NPV) observed for ruling out the risk of preeclampsia

SAN DIEGO, Nov. 20, 2020 (GLOBE NEWSWIRE) -- Progenity, Inc. (Nasdaq: PROG), a biotechnology company with an established track record of success in developing and commercializing molecular testing products in women's health is pleased to announce the company has reported clinical verification data for its Preecludia™ preeclampsia rule-out laboratory-developed test currently in development. With its performance data, including an observed 98.2% NPV, Progenity believes the Preecludia test has the potential to become the first tool of its kind in the United States to help triage possible preeclampsia, a potentially deadly condition for both pregnant mothers and their babies.

Preeclampsia is the second most common cause of maternal mortality, and more than 700,000 women present each year with signs and symptoms of possible preeclampsia. It is characterized as a hypertensive disorder, but it is difficult to differentiate from other hypertensive conditions in pregnancy, making diagnosis and management difficult. Ultimately, 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. This can result in both poor health outcomes and significant costs. The total available U.S. market for a high NPV rule-out test for preeclampsia is forecasted at up to $3 billion, and there is also a large potential global opportunity.

The Preecludia test is being developed to serve as a potential triage and rule-out test to help providers differentiate between patients with symptoms who are at risk for preeclampsia. This proprietary test is a multi-analyte protein biomarker assay which is designed to be run from a simple blood draw. In the prospective, blinded PRO-129 clinical verification study, samples were collected and analyzed from over 400 pregnant women with substantial diversity, gathered from 24 U.S. clinical sites comprised of predominantly OBGYN and Maternal Fetal Medicine (MFM) practices. Subjects presented with possible signs and symptoms of preeclampsia, including new onset hypertension, but no clear diagnosis. Subject data were independently adjudicated by a third party, and subjects, for whom preeclampsia was not diagnosed at the time of enrollment, were followed longitudinally through delivery. In subjects sampled up to 37 weeks' gestational age, the Preecludia test showed an 88.0% sensitivity, 73.3% specificity, and NPV of 98.2% at a 10% prevalence to rule out a patient's risk of developing preeclampsia within the next 14 days from the date of specimen collection. These data were generally consistent with previous results observed in the test's feasibility and optimization studies.

"The Preecludia test is the first of its kind in the United States designed to help physicians better triage symptomatic patients with suspected preeclampsia," said Harry Stylli, PhD, CEO, chairman, and co-founder of Progenity. "It is tragic that we continue to use 19 th century tools to evaluate pregnant women for diseases in the 21st century. We believe there is an obvious unmet need for new and better tools to aid in the triage, diagnosis, and management of preeclampsia. This milestone represents an important step toward our objective to commercialize the Preecludia test in the second half of 2021 and satisfy that unmet need."

Progenity previously announced the successful completion of analytical verification, which evaluated the accuracy, precision, and stability of the test's biomarker assays. The final planned step in the development program is completion of the clinical validation study. The company has already collected over 3,000 samples from more than 1,700 patients enrolled in the PRO-104 validation study, and this study is expected to begin in Q1 2021.

Progenity will provide a thorough review of preeclampsia, its cost to the healthcare system, and the Preecludia test development program during a Preeclampsia R&D Day presentation on November 20, 2020, from 8-10 AM Pacific. For further information or to access the slides presented, please visit: progenity.com/presentations.

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 on how Progenity is helping clinicians and patients prepare for life, please visit 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 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. 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 the ongoing COVID-19 pandemic and associated shelter-in-place orders, 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, the performance of third parties in connection with the commercialization and development of 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, 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, and those risks described in “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, filed with the SEC on November 11, 2020, 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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