Progenity Announces Successful Completion of Clinical Validation Study and Achievement of the Primary Endpoint for its Preeclampsia Rule-Out Test

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The company's Preecludia™ test performed strongly in a broad, intended-use population

SAN DIEGO, July 29, 2021 (GLOBE NEWSWIRE) -- Progenity, Inc. (Nasdaq: PROG), an innovative biotechnology company, announced today successful completion of the validation study for its Preecludia™ rule-out test for preeclampsia and achievement of the primary endpoint of the study protocol.

The PRO-104 clinical validation study was a prospective, multi-center, observational study with over 1,300 enrolled subjects. Test specimens were collected from pregnant patients aged 18 to 45 years and 28 0/7 to 36 6/7 weeks' gestational age. Analysis was blinded. Patients in the study cohort presented with potential signs and symptoms of preeclampsia at 20 labor and delivery triage sites across all major regions of the United States. Patient demographics were consistent with the at-risk U.S. population.

"We are proud to have achieved the primary endpoint of the PRO-104 study protocol, demonstrating that the Preecludia test can significantly distinguish between the presence and absence of preeclampsia, with the initial unblinding and analysis performed by an independent third party," said Matthew Cooper, PhD, Chief Scientific Officer, Progenity. "The test's high negative predictive value, which achieved the targeted range determined from our market research and clinician feedback, validates its utility in ruling out preeclampsia, and positions the laboratory-developed test for launch in the United States. We intend to soon publish our results in a peer-reviewed medical journal. Because of embargo considerations, we are limited in what we can share today."

Preeclampsia is the second most common cause of maternal mortality, with more than 700,000 pregnant women presenting with signs and symptoms of possible preeclampsia each year. 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. Preeclampsia is often missed or misdiagnosed because the symptoms are common – appearing in up to 30% of pregnant women in the United States – and can easily be attributed to other causes.

"Despite increasing rates of preeclampsia, there have been no significant advancements in diagnostic assessment tools in the United States in decades," stated Martin Chavez, MD, FACOG, Maternal-Fetal Medicine Specialist. "The Preecludia test will be an invaluable tool to support physicians in the differential diagnosis of patients with signs and symptoms of preeclampsia," continued Dr. Chavez, who has an active practice in high-risk obstetrics as part of a leading NYC academic medical center.

The Preecludia test is expected to target an addressable market of up to $3 billion in the United States. In addition to the laboratory-developed test (LDT) immunodiagnostic under development, this test has potential as an in vitro diagnostic (IVD) and point-of-care solution globally. Consistent with the company's recent strategic transformation, Progenity is evaluating commercialization opportunities for launch of the LDT within the United States, and IVD embodiments to access the global opportunity for the Preecludia™ test.

"We are excited to announce the successful completion of the validation study for the Preecludia test and achievement of the primary endpoint, which supports our intended use in the target patient population," said Harry Stylli, PhD, CEO, chairman of the board and co-founder of Progenity. "Successful completion of the PRO-104 study is another significant step toward equipping physicians with a valuable new tool that will transform the clinical management of patients at risk of preeclampsia and support a compelling health economic benefit for society."

About the Preecludia™ Test
The Preecludia rule-out test for preeclampsia 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 designed to be run from a simple blood draw and is intended to address the unmet need for tools to aid in the assessment and management of preeclampsia. To learn more about preeclampsia and the Preecludia test, the company's virtual R&D day webcast from November 2020 can be viewed here. Results from the Preecludia test verification study were presented at the American College of Obstetricians and Gynecologists (ACOG) 2021 Annual Meeting, and the company previously shared topline results from pre-validation testing.

About Progenity
Progenity, Inc. is a biotechnology company innovating in the fields of women's health, 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, including statements regarding the efficacy and potential utility of the Preecludia test, the timing for launch of the Preecludia test, the potential

addressable market for the Preecludia test; the potential for IVD embodiments of the Preecludia test; and any potential future commercialization opportunities. 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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