Progenity Provides Key Update Regarding its Preecludia™ Test for Preeclampsia

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Pre-validation study demonstrates commercial laboratory systems readiness; data show strong performance consistent with verification study

SAN DIEGO, May 05, 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 another key update regarding its Preecludia preeclampsia rule-out test. The company reported that its systems and processes necessary for commercial launch, including information systems, laboratory equipment, SOP finalization, and laboratory personnel training, all demonstrated commercial readiness as part of a pre-validation test. Additionally, data from this new, independent, prospective, naïve cohort examined as part of the pre-validation process showed test performance in the intended use population that was consistent with the verification study results presented April 30th at the 2021 American College of Obstetricians and Gynecologists (ACOG) Annual Meeting. The company recently announced it is in the clinical validation testing phase for the Preecludia test, with a targeted commercial 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 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. Preeclampsia can result in both poor health outcomes and significant costs.

The new data, generated with the original locked algorithm from the verification study, came from a cohort of more than 300 blinded samples equally distributed across gestational ages collected during the PRO-104 protocol, and examined as part of the pre-validation process. Analysis of these samples from the intended use population showed test performance consistent with the Preecludia verification study, indicating further de-risking of the program. The pre-validation test performance showed sensitivity greater than 87% and a negative predictive value (NPV) greater than 97% at a prevalence of 11%, and a rule out window of up to 14 days from sample collection. A similar level of performance, if observed in the larger PRO-104 validation study, would provide clinicians, especially OB/GYNs, with a new tool for their assessment of women at risk for preeclampsia. Preecludia is expected to result in a materially superior approach to the existing standard of care which offers an NPV of 83%, at best.

“We are very encouraged by the performance of the Preecludia test as evidenced in these data and prior studies. This portends well for the future performance of Preecludia in our validation study and for when we reach the commercial market,” said Harry Stylli, PhD, CEO, chairman of the board and co-founder of Progenity. “We have completed analytical testing and are initiating data analysis of the full set of patient samples from our validation study with over 1,300 patients. We plan to share the performance data from this validation study within the June/July timeframe. With these data in hand, we plan to begin a targeted launch of Preecludia in the second half of 2021 by leveraging our existing OBGYN/MFM channel.”

Progenity’s Preecludia is a preeclampsia rule-out test, not a diagnostic predictive test for preeclampsia. It 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 US market opportunity for Preecludia is estimated at up to $3 billion, with additional global market opportunities.

The ACOG poster presentation of the verification study results is available on the Progenity website.

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 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.

Investor Contact:
Robert Uhl
Managing Director, Westwicke ICR
ir@progenity.com
(619) 228-5886

Media Contact:
Angela Salerno-Robin
dna Communications
ASalerno-Robin@dna-comms.com
(212) 445-8219