Progenity Announces Patent Granted by USPTO for its Preeclampsia Rule-Out Test

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SAN DIEGO, Sept. 14, 2021 (GLOBE NEWSWIRE) -- Progenity, Inc. (Nasdaq: PROG), an innovative biotechnology company, announced today that the United States Patent and Trademark Office (USPTO) has issued U.S. Patent No. 11,112,403 for assessment of preeclampsia using assays for free and dissociated placental growth factor.

The patent is directed to methods, compositions, and kits for detecting and measuring free and dissociated placental growth factor (PlGF) levels in biological samples. PlGF is well established as an important biomarker for the assessment of preeclampsia, and recent studies have revealed the importance of distinguishing between the free and bound forms when assessing the complex physiological pathways involved in preeclampsia.

“We are pleased the USPTO has granted this patent covering unique and novel methods for determining levels of free and dissociated PlGF, since detection and quantification of both biomarkers are critical for assessing preeclampsia. This discovery helped drive the excellent performance we observed in our clinical verification and validation studies,” said Matthew Cooper, PhD, chief scientific officer of Progenity. “Patent protection is important as we pursue partnership opportunities for commercialization of the Preecludia™ test for the benefit of physicians and their patients.”

The Preecludia™ test is expected to target an addressable market of up to $3 billion annually 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. The company previouslyannounced successful completion of the clinical validation study and achievement of the primary study endpoint, and is pursuing publication of the study results in a peer-reviewed medical journal.

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.

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. The company previously shared topline results from pre-validation testing, followed by successful completion of the clinical validation study and achievement of the primary study endpoint.

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. Forward-looking statements include statements regarding Progenity’s evaluation and pursuit of partnership opportunities for the commercialization of the Preecludia™ test, the estimated addressable market size for preeclampsia and the potential uses for the Preecludia™ test in the United States and globally. 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 development process, such as the regulatory approval process, the timing of regulatory filings, the ability to identify potential partners 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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