

SERA PROGNOSTICS ANNOUNCES PUBLICATION OF THE CLINICAL VALIDATION OF PreTRM® THRESHOLD FOR CLINICAL ACTION

Publication illustrates the power of stratifying PreTRM® testing risk at or above a threshold of twice the average population risk of spontaneous preterm birth (sPTB).

Salt Lake City – November 3, 2021 – [Sera Prognostics](#) Inc., The Pregnancy Company® (NASDAQ: SERA), focused on improving maternal and neonatal health by providing innovative pregnancy biomarker information to doctors and patients, today announced the publication of a rigorous validation of a clinical decision point at spontaneous preterm birth (sPTB) risk of 15%, as determined by the company's PreTRM® test.

In the Proteomic Assessment of Preterm Risk (PAPR) study, it was demonstrated that patients at or above 15% risk, or twice the intended use population risk, had significantly higher risk of sPTB. This risk threshold was independently validated in the Multicenter Assessment of Spontaneous Preterm Birth Predictor (TREETOP) study, a completely separate cohort of patients, demonstrating that risk stratification at or above this PreTRM® threshold significantly separates higher from lower risk pregnancies. The study was conducted in accordance with the National Academy of Medicine's (NAM) guidelines for test development.

Furthermore, at or above the threshold, severe neonatal morbidity and/or mortality were significantly elevated. Identifying asymptomatic pregnancies at higher risk for sPTB and adverse maternal and neonatal outcomes is critical for reducing the enormous impact of preterm birth on health outcomes because it enables proactive interventions to occur in patients who are truly at higher risk. These new results were published in the peer-reviewed *Journal of Clinical Medicine* in an article entitled "Clinical Validation of a Proteomic Biomarker Threshold for Increased Risk of Spontaneous Preterm Birth and Associated Clinical Outcomes: A Replication Study." <https://www.mdpi.com/2077-0383/10/21/5088>

"The publication of these data adds to the growing body of evidence supporting the clinical validity and utility of Sera's PreTRM® test in identifying women at risk for sPTB and associated adverse neonatal outcomes. Sera's prospective intervention studies and health economic models are all based on a PreTRM risk threshold of approximately twice the average risk when testing is applied to populations," stated Gregory C. Critchfield, MD, MS, Chairman and CEO of Sera Prognostics. "We look forward to discussing the implications of these data as we engage with physicians, employers and payers in our efforts to improve pregnancy outcomes and reduce healthcare costs through expanded access to the PreTRM® test."

The study analysis involved the use of Sera's two large prospective clinical studies (PAPR and TREETOP), which enrolled over 10,000 subjects from 20 sites across the U.S.

Key findings of the analysis include the following for subjects with a PreTRM® score at or above the validated threshold:

- Significantly increased risk of sPTB
- Significantly increased risk of preterm birth occurring before 37, 35 and 32 weeks
- Significantly increased neonatal hospital length of stay
- Significantly increased maternal hospital length of stay
- Significantly increased severe neonatal outcomes

This validated threshold enables physicians to take action and implement a test-and-proactively-treat strategy in identifying women at risk for sPTB and offering evidence-based interventions to reduce risk, thus improving pregnancy outcomes while reducing the economic burden on payers, employers, and health care systems.

About Sera Prognostics, Inc.

Sera Prognostics is a leading health diagnostics company dedicated to improving the lives of women and babies through precision pregnancy care. Sera's mission is to deliver early, pivotal information in pregnancy to physicians, enabling them to improve the health of their patients, resulting in reductions in the costs of healthcare delivery. Sera has a robust pipeline of innovative diagnostic tests focused on the early prediction of preterm birth risk and other complications of pregnancy. Sera's precision medicine PreTRM® test reports to a physician the individualized risk of spontaneous premature delivery in a pregnancy, enabling earlier proactive interventions in women with higher risk. Sera Prognostics is located in Salt Lake City, Utah.

About Preterm Birth

Preterm birth is defined as any birth before 37 weeks' gestation and is the leading cause of illness and death in newborns. The 2020 March of Dimes Report Card shows that of approximately 3.8 million babies born annually in the United States, more than one in ten is born prematurely. Prematurity is associated with a significantly increased risk of major long-term medical complications, including learning disabilities, cerebral palsy, chronic respiratory illness, intellectual disability, seizures, and vision and hearing loss, and can generate significant costs throughout the lives of affected children. The annual health care costs to manage short- and long-term complications of prematurity in the United States were estimated to be approximately \$25 billion for 2016.

About the PreTRM® Test

The PreTRM® test is the only broadly clinically validated, commercially available blood-based biomarker test that provides an early, accurate and individualized risk prediction for spontaneous preterm birth in asymptomatic singleton pregnancies. The PreTRM® test measures and analyzes proteins in the blood that are highly predictive of preterm birth. The PreTRM® test permits physicians to identify, during the 19th or 20th week of pregnancy, which women are at increased risk for preterm birth, enabling more informed, personalized clinical decisions based on each woman's individual risk. The PreTRM® test is ordered by a medical professional.

Sera Prognostics, the Sera Prognostics logo, The Pregnancy Company, and PreTRM are trademarks or registered trademarks of Sera Prognostics, Inc in the U.S. and/or other countries.

Safe Harbor Statement

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to discussing these data with physicians, employers and payers; and the company's strategic directives under the caption "About Sera Prognostics, Inc." These "forward-looking statements" are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by forward-looking statements. These risks and uncertainties include, but are not limited to: net losses, cash generation, and the potential need to raise more capital; revenues from the PreTRM test representing substantially all Company revenues to date; the need for broad scientific and market acceptance of the PreTRM test; a concentrated number of material customers; our ability to introduce new products; potential competition; our proprietary biobank; critical suppliers; the ongoing COVID-19 pandemic and its impact on our operations, as well as the business or operations of third parties with whom we conduct business; estimates of total addressable market opportunity and forecasts of market growth; potential third-party payer coverage and reimbursement; new reimbursement methodologies applicable to the PreTRM test, including new CPT codes and payment rates for those codes; changes in FDA regulation of laboratory-developed tests; the intellectual property rights protecting our tests and market position; and other factors discussed under the heading "Risk Factors" contained in our Final Prospectus on Form S-1, which was filed with the Securities and Exchange Commission on July 14, 2021, as well as any updates to those risk factors filed from time to time in our Quarterly Reports on Form 10-Q, Annual Reports on Form 10-K, or Current Reports on Form 8-K. All information in this press release is as of the date of the release, and the Company undertakes no duty to update this information unless required by law.

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