

SERA PROGNOSTICS AND NEWBORN FOUNDATION PARTNER TO REDUCE RISKS ASSOCIATED WITH PRETERM BIRTH AND IMPROVE HEALTH EQUITY THROUGH THE "EVERY MOTHER, EVERY BABY" PROJECT

Project focused on reducing maternal and neonatal mortality and morbidity by mitigating risks associated with unanticipated preterm birth

SALT LAKE CITY, May 5, 2022 /[PRNewswire](#)/ -- 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, and the Newborn Foundation today announced the launch of the *Every Mother, Every Baby* Project.

The *Every Mother, Every Baby* Project, developed by the Newborn Foundation in partnership with Sera, is designed to educate clinical practitioners, policymakers, and public health stakeholders about the critical role that validated biomarker-based preterm risk assessment tests like Sera's PreTRM® test can play in improving neonatal and maternal health outcomes. The Newborn Foundation will work collaboratively with industry and public health stakeholders to advance the educational, policy and implementation framework around earlier recognition of risks associated with preterm birth as a means to improve health equity and achieve commitments to the United Nations' Sustainable Development Goals.

The announcement comes on the heels of a 2-day forum in which the Newborn Foundation convened maternal and newborn health stakeholders to define 2022 domestic and global health policy priorities.

"Neonatal mortality is the leading cause of preventable child death globally. More than 60% of infant deaths occur during the neonatal period, and 35% of all deaths among newborns are caused by being born too soon," said Annamarie Saarinen, CEO of the Newborn Foundation. "Biomarker tests that identify women at risk of preterm birth and enable risk-reduction interventions are essential for reducing neonatal mortality and improving outcomes. The *Every Mother, Every Baby* Project will help answer the key questions needed to ensure broad and affordable access to these tests regardless of a pregnant woman's geographic or socioeconomic status. We are pleased to partner with Sera and other global health stakeholders to achieve this important goal."

The *Every Mother, Every Baby* Project is designed to achieve three key objectives:

- Reduce maternal and newborn mortality through mitigation of risks associated with unanticipated preterm birth.
- Deploy an effective, efficient, and scalable provider and public health education program focused on the role of biomarker tests in assessing the risk of preterm birth.
- Provide data needed to support governmental and public health policies and funding initiatives to ensure equitable access and appropriate standardized prenatal biomarker testing reimbursement.

"The Newborn Foundation is a recognized leader in its work to improve newborn and infant health, both in the United States and around the world. We are excited to partner with an organization that shares our belief in the power of validated biomarker-based approaches to better assess preterm birth risk proactively, months ahead of its occurrence, and to mitigate its adverse consequences," said Gregory C. Critchfield, MD, MS, Chairman and CEO of Sera Prognostics. "We are eager to work productively together with the Foundation and other key stakeholders in important efforts to reduce health disparities and to better address the global challenges of neonatal morbidity and mortality."

The PreTRM® test was developed and broadly validated in the U.S. for predicting spontaneous preterm birth (sPTB) in the Proteomic Assessment of Preterm Risk (PAPR) study. Recently, published data from the multinational AMANHI study of pregnancies in South Asia and sub-Saharan Africa demonstrate that Sera biomarkers can stratify spontaneous preterm births in populations outside of the United States. Additional work on the biomarkers demonstrates their ability to predict very early preterm birth of all causes, gestational age at birth, length of neonatal hospital stay, and neonatal morbidity and mortality; in a large U.S. prospective study, the Multicenter Assessment of a Spontaneous Preterm Birth Risk Predictor (TREETOP) study. Furthermore, clinical utility and economic utility of Sera's biomarker approach have been the subject of multiple published studies.

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, and to reduce 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 Newborn Foundation

The [Newborn Foundation](#) is focused on early identification of health conditions and equitable access to care through education, advocacy, research, and public health initiatives. Since inception in 2010, we have championed streamlined, multi-stakeholder approaches to ensuring safe and effective innovations reach babies, families, and clinicians.

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 2021 March of Dimes Report Card shows that of approximately 3.6 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.

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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 the Newborn Foundation's work to advance the educational, policy and implementation framework to improve health equity and achieve commitments to the United Nations' Sustainable Development Goals; the *Every Mother, Every Baby* Project helping to answer the key questions needed to ensure broad and affordable access to these tests regardless of a pregnant woman's geographic or socioeconomic status; ensuring equitable access and appropriate standardized prenatal biomarker testing reimbursement; 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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