

SERA PROGNOSTICS ANNOUNCES PRIMARY ENDPOINT CRITERIA MET IN PIVOTAL PRIME STUDY INTERIM LOOK - ENROLLMENT TO STOP DUE TO SUCCESS

SALT LAKE CITY, Dec. 6, 2023 /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, today announced that the Data Safety Monitoring Board (DSMB) overseeing its pivotal [Prematurity Risk Assessment Combined with Clinical Interventions for Improved Neonatal Outcomes \(PRIME\)](#) study recommended stopping enrollment due to efficacy, reporting that either of the co-primary endpoints met the stopping criteria for statistical significance at the pre-planned interim analysis. The Company has adopted the DSMB's recommendation and will stop PRIME study enrollment to focus on analyzing and reporting the available data.

"We are excited by this report of efficacy from the DSMB," said Zhenya Lindgardt, President and CEO of Sera Prognostics. "It is unexpected for trials to stop early for efficacy since most statistical power is typically reserved for the final analysis, which makes this event that much more encouraging. We look forward to sharing top-line results once we have had a chance to analyze the interim look data. We believe this will add to the PREVENT and AVERT studies in the growing, consistent body of evidence for our PreTRM[®] test that advances our mission to save lives and improve health for mothers and babies across the globe."

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 provide early, pivotal pregnancy information to improve the health of mothers and newborns, 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 headquartered 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 2022 March of Dimes Report Card shows that, for the last four consecutive years, more than one in ten infants 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 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 weeks 18 through 20 of pregnancy, which women are at increased risk for preterm birth and its complications, 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 United States 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 stopping PRIME study enrollment; analyzing and reporting the available data; sharing top-line results from the interim look data; the interim look adding to the PREVENT and AVERT studies in the growing, consistent body of evidence for the PreTRM[®] test; advancing the Company's mission to save lives and improve health for mothers and babies across the globe; 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 COVID-19 pandemic and its potential lingering 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.

SOURCE Sera Prognostics, Inc.

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