Sera Prognostics PreTRM® Test Prevention Strategy Demonstrates 18% Reduction in Severe Neonatal Morbidity and Mortality in Newly Published AVERT Trial

Sera Prognostics Announces Publication of Positive AVERT PRETERM TRIAL Results in the International Peer-Reviewed Journal, *Diagnostics*

SALT LAKE CITY, July 9, 2024 /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 the publication in *Diagnostics*, an international, peer-reviewed, open access journal on medical diagnosis, of the top-line results from the AVERT PRETERM TRIAL (Serum Assessment of Preterm Birth Outcomes Compared to Historical Controls), conducted at ChristianaCare in Wilmington, Delaware.

PreTRM® test-and-treat strategy demonstrates statistically and clinically significant improvement in neonatal health outcomes and hospital length-of-stay

Previously, Sera reported that both co-primary outcomes—reduction of severe neonatal morbidity or neonatal death; and decreased length of neonatal hospital stay—met their endpoints, and the improvements in outcome with a PreTRM® test-and-treat approach were statistically significant. Notably, results from the AVERT PRETERM TRIAL indicated:

- An 18% reduction in severe neonatal morbidity and mortality,
- A 7-day reduction in mean neonatal hospital length of stay,
- Increased average gestational age at birth before 32 weeks of 2.48 weeks,
- And a 28-day reduction in neonatal length of hospital stay for babies born before 32 weeks' gestation, reducing time spent in the hospital for those at risk of earliest delivery.

The manuscript also reports that neonatal morbidity and mortality and hospital and NICU length of stay were significantly reduced in the entire intent-to-treat population. The test and treat strategy was associated with a decreased odds of preterm birth and spontaneous preterm birth at various gestational ages at birth and an average NICU length of stay savings of 0.6 days per pregnancy across all pregnancies tested.

"These results suggest that biomarker spontaneous preterm birth risk stratification and preventive interventions can ameliorate preterm birth complications in singleton, often nulliparous, pregnancies historically deemed low risk," said Dr. Matthew Hoffman, Marie E. Pinizzotto, M.D., Endowed Chair, Department of Obstetrics & Gynecology, Director, Center for Women & Children's Health Research, ChristianaCare, the study's principal investigator.

"The AVERT PRETERM TRIAL results demonstrate for the first time that the health of babies can be improved in asymptomatic pregnant mothers without typical risk factors by the combination of biomarkers for spontaneous preterm birth risk and targeted interventions," said Zhenya Lindgardt, President and CEO of Sera Prognostics. "We are delighted to have published these clinically significant results in *Diagnostics*. We are now actively engaged in analyzing our final PRIME study results to continue to enrich an already broad portfolio of evidence for our PreTRM® test-and-treat strategy in improving maternal and neonatal care while reducing healthcare costs."

Update on Sera Prognostics PRIME Study

As Sera announced in December 2023, the Data Safety and Monitoring Board (DSMB) overseeing the Company's 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. Sera Prognostics noted in May 2024 that deliveries of PRIME study participants, the remaining 2,200 who were enrolled before enrollment stopped per DSMB recommendation, were complete and all mothers and babies within the study have left the hospital and data gathering for the final PRIME results has begun.

About the AVERT PRETERM TRIAL

The AVERT PRETERM TRIAL evaluated the health benefit afforded to babies when pregnancies are screened with the PreTRM® Test and physicians intervened based on those results. An active arm of approximately 1,463 expectant mothers in the ChristianaCare in Delaware was tested in mid-pregnancy to stratify for increased risk of spontaneous preterm birth risk and those at higher risk were offered evidence-based interventions, which included care management,

more intensive education, and medications. A historical control arm of approximately 10,000 patients was drawn from the immediate 2-year period before the trial enrollment began. Important neonatal outcomes that included total neonatal length of hospital stay and composite neonatal morbidity/mortality were analyzed in the active and historical control arms.

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 and digital tools 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 2023 March of Dimes Report Card shows that, for the last five consecutive years, more than one in ten infants is born prematurely in the United States. 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 healthcare 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.

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 final PRIME study results enriching an already broad portfolio of evidence for our PreTRM® test-and-treat strategy; additional milestones in advancing the Company's role to improve maternal and neonatal healthcare outcomes; 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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https://investors.seraprognostics.com/2024-07-09-Sera-Prognostics-PreTRM-R-Test-Prevention-Strategy-Demonstrates-18-Reduction-in-Severe-Neonatal-Morbidity-and-Mortality-in-Newly-Published-AVERT-Trial