Sera Prognostics Announces Positive Top-line Data from AVERT PRETERM TRIAL

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

SALT LAKE CITY, Feb. 15, 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 top-line results from the AVERT PRETERM TRIAL (Serum Assessment of Preterm Birth Outcomes Compared to Historical Controls), conducted at ChristianaCare in Wilmington, Delaware.

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. Detailed results of the AVERT PRETERM TRIAL analysis are being prepared for publication in a peer-reviewed journal.

"The AVERT PRETERM TRIAL results demonstrate the generalizability of the PreTRM® test-and-treat strategy in achieving meaningful clinical results in widely diverse U.S. populations," said Gregory C. Critchfield, MD, MS, Chairman and CEO of Sera Prognostics. "Furthermore, these important AVERT PRETERM TRIAL clinical results build on and reinforce those of past studies—including PAPR, TREETOP and PREVENT-PTB. We believe the AVERT PRETERM TRIAL findings add to the growing body of evidence for the PreTRM® Test's clinical benefit to mothers and babies, and that these new results bode well for our ongoing, large multi-center PRIME study."

The PreTRM® Test was broadly developed and validated for prediction of spontaneous preterm birth (sPTB) in the U.S. in the Proteomic Assessment of Preterm Risk (PAPR) study. In a subsequent large prospective U.S. study, the Multicenter Assessment of a Spontaneous Preterm Birth Risk Predictor (TREETOP), the biomarkers were demonstrated to be predictive of very early preterm birth of any cause, neonatal length of hospital stay, and composite neonatal morbidity/mortality. Additional data published in May 2022 showed improved PreTRM® Test predictive performance for women whose due dates are more reliably determined by ultrasound.

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 1,453 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 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 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, 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 preparation of detailed results of the AVERT trial for publication in a peer-reviewed journal; the AVERT findings adding to the growing body of evidence for the PreTRM test's clinical benefit to mothers and babies; the Company's view that the new AVERT results bode well for the ongoing, large multi-center PRIME study; 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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