Sera Prognostics' PreTRM® Test and Treat Strategy Benefits Demonstrated by Results of Prospective, Randomized Controlled Intervention Trial Evaluating Clinical Utility

Study demonstrates positive impact of the company's PreTRM® test and treat strategy on improving neonatal healthcare
- NICU and total hospital length-of-stay in preemies reduced by more than 70% - Faster rate of discharge from the NICU for spontaneous preterm deliveries, any preterm deliveries, and all infant deliveries, respectively - Severe morbidity or newborn death reduced by 66% across all affected infants

SALT LAKE CITY, Aug. 17, 2021 (GLOBE NEWSWIRE) — Sera Prognostics Inc., The Pregnancy Company™, focused on improving maternal and neonatal health by providing innovative pregnancy biomarker information to doctors and patients, today announced the publication, in the *American Journal of Perinatology (AJP),* *https://www.thieme-connect.com/products/ejournals/html/10.1055/s-0041-1732339* of results of the Prediction and Prevention of Preterm Birth (PREVENT-PTB) Study, a prospective, randomized controlled intervention trial conducted between May 2018 through February 2019. The purpose of the trial was to evaluate the impact on neonatal health and economics of applying the company's PreTRM® test to screen pregnant women for risk of spontaneous preterm birth (sPTB) and treating the women identified at higher risk with proactive interventions. Trial results showed that using PreTRM® to identify and treat those with higher risk pregnancies proactively may lead to better neonatal outcomes.

"We are pleased with the results of this ground-breaking trial and thank the investigators and patients who participated in this study," stated Gregory C. Critchfield, MD, MS, Chairman and CEO of Sera Prognostics. "This study is the first time that a prognostic biomarker blood test for preterm delivery risk has been evaluated for its potential impact on important outcomes of neonatal health that have large economic consequences. The study results show that promising improvements were obtained by using the PreTRM® test to identify higher risk patients and to intervene more proactively in these pregnancies using well-understood interventions. We believe that these results show that more proactive treatment in patients whose elevated risks are real, but not readily apparent with current clinical methods, can make a positive difference in pregnancy."

The PREVENT-PTB study, conducted at Intermountain Healthcare, in Salt Lake City, Utah, enrolled 1,208 pregnant patients from May 2018 through February 2019, who were 18 years or older, with a singleton pregnancy in the 19th or 20th week of gestation, and with no history of prior preterm birth and normal cervical length at or before the time of enrollment. Of the 1,181 women ultimately randomized and for whom outcome data were available, 589 pregnancies were in the PreTRM test-screened arm, and 592 served as controls not having access to the test. Patients whose PreTRM test result risk met or exceeded twice the population risk were deemed "higher risk," and were offered a group of proactive interventions. These included weekly contact with a care management nurse, two preterm prevention clinic visits, cervical length monitoring, weekly injection of 17-alpha-hydroxyprogesterone caproate, daily administration of low-dose aspirin, and the administration of corticosteroid treatment if patients indicated clinical signs or symptoms of imminent delivery. Patients in the screened group found not to be at higher risk by the PreTRM® test received standard obstetrical care. The control group did not receive the PreTRM® test and received standard obstetrical care only.

Due solely to limited financial resources at the time, the trial was stopped early, prior to data unblinding. As a result of early termination, the trial enrolled 1,208 patients, short of the originally projected enrollment between 3,000 – 10,000 patients required in order to provide sufficient statistical power to evaluate the study's originally conceived primary outcome of spontaneous preterm delivery before 37 weeks. However, a number of pre-defined non-primary outcomes of major neonatal clinical importance were sufficiently powered to demonstrate the positive impact of the test and treat strategy, and revealed consistent benefit across different neonatal outcomes (without correction for multiple testing, as pre-specified). These outcomes included measures of length of stay in neonatal intensive care unit (NICU) and overall hospital length of stay, among others.

The PREVENT-PTB topline results were reported in a late-breaking poster session at the 2020 annual meeting of the Society for Reproductive Investigation. The AJP article, published online August 16, 2021, contained a more complete report of key findings of the study. Despite an unexpectedly low rate of spontaneous preterm birth of 3.5% in the control group, the following differences were seen between the PreTRM-screened arm and the control (unscreened) arm in the study:

- The authors reported 23-80% reductions in preterm delivery rates occurring before 37, 35 and 32 weeks of pregnancy. These reductions were seen in either spontaneous deliveries alone or in any preterm deliveries, which also includes medically-indicated preterm deliveries. While the company believes that these reductions across different levels of prematurity are encouraging, the study was not adequately powered to evaluate whether these rate reductions were statistically significant.

- A statistically significant reduction in median NICU (newborn intensive care unit) length-of-stay for spontaneous preterm deliveries admitted to the NICU from 45.5 to 6.8 days (an 85% reduction)
- A statistically significant reduction in median NICU length-of-stay for any preterm delivery admitted to the NICU (includes spontaneous preterm delivery and medically-indicated preterm delivery) from 36.7 to 7.6 days (a 79% reduction)
- Statistically significant faster rate of discharge from the NICU for spontaneous preterm deliveries, any preterm deliveries, and all deliveries, respectively
- A reduction in total NICU number of days incurred in preterm infants admitted to the NICU from 619 to 172 (a 72% reduction)
- A reduction in total neonatal hospital number of days incurred in preterm infants from 700 to 204 (a 71% reduction)
- In infants affected by any degree of impairment associated with prematurity (mild, moderate, severe or neonatal death), severe morbidity/mortality was reduced from 14/70 (20.0%) in the control arm to 5/73 (6.8%) in the screened arm (a relative reduction of 66%).

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.

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 use of PreTRM® testing potentially leading to better neonatal outcomes; more proactive treatment in patients identified as at higher risk using the PreTRM® test potentially making a positive difference in pregnancy; 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.

Contact

Erich Sandoval, Lazar FINN

erich.sandoval@finnpartners.com

+1 917 497 2867
