

Sera Prognostics to Present PRIME Study Results at 2025 SMFM Pregnancy Meeting

SALT LAKE CITY, Dec. 4, 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 that the results of the PRIME study were accepted as a late-breaking abstract for oral podium presentation at the [Society for Maternal-Fetal Medicine 2025 Pregnancy Meeting™](#) on [January 31, 2025 at 10:15 a.m. MT](#). Dr. Brian Iriye – maternal-fetal medicine expert at the High Risk Pregnancy Center in Las Vegas, Nevada, and principal investigator for the PRIME study – will present the results of the full PRIME study.

The study – [Prematurity Risk Assessment Combined with Clinical Interventions for Improved Neonatal Outcomes \(PRIME\)](#) – evaluated how pairing the PreTRM test, used to identify pregnant women who are at higher risk of delivering preterm, with targeted clinical interventions may affect neonatal outcomes. The Company announced in December 2023 that it had stopped enrollment for the PRIME study following notice from the Data Safety Monitoring Board that the pre-planned interim analysis achieved at least one of its primary endpoints at the required level of statistical significance. Since then, the Company has focused on data gathering and analysis for the complete cohort enrolled before the December 2023 stoppage, ultimately submitting a late-breaking abstract last month for SMFM's consideration.

"Sera is honored that data for its PreTRM® test will be presented from the podium at SMFM," said Zhenya Lindgardt, President & CEO of Sera Prognostics. "This is a prestigious conference, and exactly the right platform from which to share these results with the community."

The annual Pregnancy Meeting™ is the centerpiece of the Society for Maternal-Fetal Medicine's work and widely considered the world's leading conference on the subject of pregnancy, featuring postgraduate courses and workshops, luncheon roundtables, scientific forums, oral and poster presentations, industry learning, exhibits, and more. The PRIME abstract, one of five selected for presentation in late-breaking oral sessions, is expected to be published by SMFM ahead of the meeting in mid-January 2025.

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 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 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 Dr. Brian Iriye presenting the results of the PRIME study at the podium at the Society for Maternal-Fetal Medicine 2025 Pregnancy Meeting on January 31, 2025 at 10:15 a.m. MT; the SMFM Pregnancy Meeting being exactly the right platform from which to share PRIME results with the community; publication of the PRIME abstract by SMFM ahead of the meeting in mid-January 2025; 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 Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission, as well as any updates to those risk factors filed from time to time in our periodic and current reports filed with the Securities and Exchange Commission. 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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