

# ***SERA PROGNOSTICS ANNOUNCES PUBLICATION OF DATA PREDICTING CLINICAL UTILITY AND COST EFFECTIVENESS OF THE PRETRM® TEST-AND-TREAT STRATEGY ACROSS DIVERSE POPULATIONS***

*- Clinical and economic benefits of the PreTRM® test and treat strategy illustrated amongst diverse racial and ethnic backgrounds -*

SALT LAKE CITY, Nov. 15, 2022 [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 of results from a clinical utility and cost-effectiveness modeling study, ACCORDANT (Analyses aCross Congruent studies ReDucing Adverse pregnancy ouTcomes). The newly published study reports:

- Case management, which consists of increased outreach, education, and specialist care for women predicted to be at higher risk for delivering prematurely, was expected to decrease neonatal and maternal hospital length of stay by 19% (p=0.029) and 8.5% (p=0.001), respectively, compared with standard care.
- Case management for those at higher risk also was predicted to significantly reduce moderate-to-severe neonatal morbidity and mortality by 29% (p=0.025).
- Multimodal management, which combines case management with pharmacological treatment, was predicted to further improve outcomes and statistical significance
- The modeled clinical benefits and cost-effectiveness of the test-and-treat strategies were seen across diverse racial and ethnic backgrounds, with Black and Hispanic women strongly represented in the study.

"Results of this analysis point to the utility of the PreTRM® test-and-treat strategy in ameliorating the clinical and economic effects of preterm delivery, which impacts more than 10% of U.S. births each year," said Gregory C. Critchfield, MD, MS, Chairman and CEO of Sera Prognostics. "Most importantly, the predicted benefits across underserved populations, among whom the prevalence of preterm birth is disproportionately increased, provide the opportunity to serve a broad and diverse population of women in the United States. We are excited to be in a position to help substantively address unacceptable healthcare disparities in pregnant populations that unfortunately bear the burdens of prematurity."

"By combining the PreTRM® Test, which detects far more women at risk of preterm birth than traditional clinical factors, with enhanced prenatal case management, real progress may be possible for this under-addressed and serious condition," said Michael Foley, MD, Sera's Chief Medical Officer.

ACCORDANT was a secondary analysis of 847 women from the Multicenter Assessment of a Spontaneous Preterm Birth Risk Predictor study (TREETOP), a previously published evaluation of the predictive performance of the PreTRM® Test. The study combined real-world clinical information with large, published outcomes datasets in a microsimulation model to examine the potential impacts of the test-and-treat strategies on important clinical indicators and medical costs related to preterm birth.

The peer-reviewed report, "Clinical and economic evaluation of a proteomic biomarker preterm birth risk predictor: Cost-effectiveness modeling of prenatal interventions applied to predicted higher-risk pregnancies within a large and diverse cohort," was published in the *Journal of Medical Economics* (<https://www.tandfonline.com/doi/full/10.1080/13696998.2022.2147771>).

## **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 2021 March of Dimes Report Card shows that 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 enables physicians to identify, during the 18th through the 20th week of pregnancy, which women are at increased risk for preterm birth, driving more informed and personalized clinical decisions based on each woman's individual risk. The PreTRM® Test is ordered by a medical professional.

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### **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 performance of the PreTRM® test predicted in the model used in the ACCORDANT 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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