

SERA PROGNOSTICS ANNOUNCES PUBLICATION OF DATA CONFIRMING THE PERFORMANCE OF THE IBP4/SHBG BIOMARKERS IN DIVERSE NON-U.S. POPULATIONS

Results confirmed that a U.S. validated proteomics predictor could be applied in low and middle income countries to help address global preterm birth challenges

Salt Lake City, – December 1, 2021 – [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 a study funded by the Bill & Melinda Gates Foundation and in collaboration with AMANHI (Alliance for Maternal and Newborn Health Improvement), a multinational effort to improve health for pregnant and postpartum women and their babies in sub-Saharan Africa and South Asia. The newly published article presents the performance of the IBP4/SHBG biomarker pair in predicting spontaneous preterm birth (sPTB) in low and middle income geographies, with prespecified adjustment for demographic differences between the populations.

“Sera is committed to addressing the global challenges of premature births,” said Gregory C. Critchfield, MD, MS, Chairman and CEO of Sera Prognostics. “The data published today demonstrate that our biomarkers can be used to predict sPTB in patient populations with baseline demographics and health care access that are distinct from those of U.S. populations in which they were initially validated. We believe that these data warrant careful consideration by all stakeholders who seek to improve maternal and neonatal outcomes and support the further evaluation of these biomarkers in additional populations.”

The PreTRM® test was developed and validated for prediction of spontaneous preterm birth (sPTB) broadly in the U.S. in the Proteomic Assessment of Preterm Risk (PAPR) study. The biomarkers were subsequently shown to be predictive of very early preterm birth of any cause, length of neonatal hospital stay, and neonatal morbidity and mortality in a second large prospective U.S. study, the Multicenter Assessment of a Spontaneous Preterm Birth Risk Predictor (TREETOP) study. Now, analysis of biomarker performance in AMANHI samples, published in the peer-reviewed *Journal of Maternal-Fetal & Neonatal Medicine* in an article entitled “Performance of a validated spontaneous preterm delivery predictor in South Asian and sub-Saharan African women: a nested case-control study”: <https://doi.org/10.1080/14767058.2021.2005573> demonstrates confirmation of PreTRM biomarker predictive performance for prematurity with prespecified adjustment for expected demographic differences in populations outside of the United States.

The AMANHI biobanking study enrolled 10,001 pregnant women in Bangladesh, Pakistan, and Tanzania from whom a nested case control analysis was conducted in 298 representative pregnancies. This work demonstrated that IBP4 and SHBG, the biomarkers utilized by the U.S. PreTRM® test, after prespecified adjustment for expected demographic differences between the populations, significantly predicted sPTB. As was demonstrated in the U.S. studies, the biomarkers performed well for prediction of sPTB <37 weeks and for earlier more severe preterm births. The new publication further demonstrates the strength of Sera’s artificial intelligence pipeline by the identification of a limited number of additional biomarkers that complement IBP4 and SHBG biomarker in predictive performance for prematurity in this diverse cohort with blood draws earlier in gestation. The IBP4/SHBG biomarker pair may have broader application for predicting sPTB in diverse non-U.S. populations.

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.

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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 broader application of the IBP4/SHBG biomarker pair for predicting sPTB in diverse non-U.S. populations; 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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