# SERA PROGNOSTICS ANNOUNCES PRICING FOR PRETRM® TEST, THE ONLY BROADLY VALIDATED BLOOD TEST TO ASSESS RISK OF PRETERM BIRTH

## - New Assigned Rate Further Validates the Commercial Value of the PreTRM® Test -

Salt Lake City – Dec 2, 2021 – <u>Sera Prognostics</u> 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 Centers for Medicare & Medicaid Services (CMS) has set a Medicare payment rate for the existing unique Proprietary Laboratory Analysis (PLA) code, 0247U, for the PreTRM® Test, the company's proprietary proteomic blood test for measuring a woman's risk of spontaneous preterm birth to allow more timely intervention. This payment rate for the 0247U code is scheduled to go into effect on January 1, 2022 and is expected to apply for CY 2022, at a rate of \$750.00. The establishment of a price, while reinforcing the value of the PreTRM® test, does not necessarily mean the test will be covered by Medicare or any other payer. Medicare coverage of a test requires either a local or national coverage decision.

PLA codes are an addition to the CPT code set approved by the American Medical Association (AMA) CPT Editorial Panel. The codes are alpha-numeric CPT codes with corresponding descriptors for labs wishing to identify their respective tests more specifically. Additional information surrounding the billing and coding article related to the Clinical Laboratory Fee Schedule (CLFS) test codes final pricing determination for the PreTRM® test for CY 2022 is available on the CMS website under 'Final Payment Determinations.'

"Even though Medicare beneficiaries are not expected to be a large portion of the market for PreTRM® test, the Medicare-determined price is additional evidence of the value of PreTRM® testing and is an important step in our commercial strategy to continue to establish the PreTRM® reimbursement framework," said Gregory C. Critchfield, MD, MS, chairman and chief executive officer of Sera Prognostics. "Building on Medicare's pricing determination, we will continue negotiations with commercial, self-insured and governmental insurance programs, including Medicaid, as we work to provide patients with broader access to this important test. The PreTRM® test improves identification of pregnancies at higher risk of prematurity to enable earlier proactive interventions to decrease adverse outcomes in Sera's quest to improve the well-being of mothers and babies and to decrease healthcare costs."

## 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 the Medicare payment rate going into effect on January 1, 2022 and applying for CY 2022; the Company continuing to establish the reimbursement framework for the PreTRM® test; building on Medicare's pricing determination; continuing negotiations with commercial, selfinsured and other governmental insurance programs, including Medicaid; providing patients with broader access to the PreTRM® test; 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 Investor Contact Peter DeNardo, CapComm Partners peter@capcommpartners.com +1 (415) 389-6400

Media Contact Erich Sandoval, Lazar FINN <u>Erich.sandoval@finnpartners.com</u> +1 (917) 497-2867

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