Shuwen Biotech Announces South African Clinical Study of CercaTest RED™ for Short-Term Prediction of Preeclampsia

DEQING, CHINA, July 21, 2026 /EINPresswire.com/ -- Shuwen Biotech today announced the initiation of a prospective clinical study by leading experts in South Africa evaluating CercaTest RED™, its novel point-of-care urine test for misfolded proteins, for the short-term prediction of preeclampsia in women at high risk presenting with suspected preeclampsia.

> This study marks another important milestone in our mission to make innovative, rapid, accessible, and affordable preeclampsia risk assessment available to pregnant women worldwide."
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> *Jay Z. Zhang, Executive Chairman, Shuwen Biotech*

Preeclampsia is one of the leading causes of maternal and perinatal morbidity and mortality worldwide, affecting an estimated 2–8% of pregnancies. The burden is particularly severe in sub-Saharan Africa, where an estimated 5-10% of pregnancies are complicated by preeclampsia, affecting 2-5 million women each year. Women presenting with suspected preeclampsia often require intensive monitoring or hospitalization because clinicians currently have limited tools to accurately identify those at greatest risk of disease progression. A rapid point-of-care test capable of predicting short-term risk could support earlier clinical decision-making, improve patient triage, and help optimize healthcare resources, particularly in low- and middle-income countries.

Unlike laboratory-based biomarker tests that require specialized instrumentation and centralized laboratories, CercaTest RED™ detects urinary misfolded proteins from a simple urine sample and delivers results within minutes at the point of care. Its instrument-free design makes it particularly well suited for decentralized healthcare facilities and resource-limited settings.

The study is led by Professor Jagidesa ("Jack") Moodley of the University of KwaZulu-Natal and Dr. Olive Khaliq of the University of the Free State, internationally recognized experts in maternal-fetal medicine and hypertensive disorders of pregnancy in Africa. Previous studies in Oxford University, Zhejiang University Women's Hospital, and Shengjing Hospital have demonstrated in European and Chinese populations the good performance of CercaTest RED™ in diagnosing and short-term prediction of preeclampsia. The South African study will evaluate the clinical performance of CercaTest RED™ in Africans for screening high risk women and identifying women at imminent risk of developing preeclampsia, enabling timely intervention while helping

reduce unnecessary hospitalization and optimizing the use of healthcare resources.

The South African study represents the second clinical validation of CercaTest RED™ in Africa, following the ongoing PROTECT-Africa study (PROgnostic Testing to Enhance Clinical Triage of Pre-eclampsia in Africa) in Zimbabwe, Rwanda, and Tanzania by the Africa Clinical Research Network (ACRN). Together, these studies are expanding the clinical evidence supporting CercaTest RED™ across diverse African populations and healthcare settings, where the burden of maternal morbidity and mortality from preeclampsia remains among the highest in the world.

The South African study complements both the ongoing ACRN study in Africa and the PRE-CERCA multicenter clinical study to be initiated in Southeast Asia, extending Shuwen Biotech's global clinical validation program for CercaTest RED™ across multiple continents and diverse patient populations. Together, these studies are expected to generate one of the most comprehensive multinational clinical evidence packages supporting the use of urinary misfolded protein testing for the prediction and clinical management of preeclampsia.

"We are honored to support the study by Professor Moodley and Dr. Khaliq, two of Africa's leading experts in hypertensive disorders of pregnancy," said Jay Z. Zhang, Executive Chairman of Shuwen Biotech. "Their leadership and extensive experience in maternal health research make them ideal experts for evaluating CercaTest RED™ in a real-world clinical setting in Africa. This study marks another important milestone in our mission to make innovative, rapid, accessible, and affordable preeclampsia risk assessment available to pregnant women worldwide."

About CercaTest RED™

CercaTest RED™ is a next-generation point-of-care urine test developed by Shuwen Biotech for the rapid detection of urinary misfolded proteins associated with preeclampsia. Using a simple urine sample, the test provides results within minutes without the need for laboratory equipment or specialized personnel. CercaTest RED™ is designed to screen high risk women and support identification of women at imminent risk of developing preeclampsia in hospitals, outpatient clinics, and community healthcare settings worldwide, enabling timely intervention.

About Shuwen Biotech

Shuwen Biotech is an integrated biotech company with offices in China and Germany. Founded on the principles of innovation, patent protection, and international collaboration, Shuwen established strategic partnerships with leading academic and commercial institutions to commercialize first-in-class diagnostic technologies and patents, and has developed a range of novel diagnostics in the fields of cancer and women's health. Shuwen has also developed quality companion diagnostics and provides central lab biomarker testing services to leading pharmaceutical developers and hospitals. Shuwen houses an in-house development team, CAP-accredited central labs, and GMP/ISO13485-certified IVD manufacturing facilities, all in line with global standards to continue to deliver transformational products and services to its customers globally and open new possibilities in the advancement of health. Innovative products are also offered on the international market through Cerca Biotech GmbH (www.cercabiotech.com),

Shuwen’s European subsidiary in Berlin.

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