Shuwen Biotech Announces NMPA Approval for Pre-eclampsia Point of Care Test

CercaTest RED Pre-eclampsia Test Approved for both Professional Use and Self-testing at Home

CHINA, July 30, 2024 /EINPresswire.com/ -- Shuwen Biotech, an integrated in vitro diagnostic (IVD) company today announced that it has received approval from the National Medical Products Association (NMPA)1 approval for the CercaTest RED Pre-eclampsia Test, for Professional use in medical institutions and self-testing at home.

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> *Jay Z. Zhang, MS, JD*

Pre-eclampsia is a hypertensive syndrome that occurs in pregnant women, most often after 20 weeks' gestation, which consists of new-onset, persistent hypertension with either proteinuria or evidence of systemic involvement. Preeclampsia complicates 2 to 8% of all pregnancies and accounts for about 70,000 maternal deaths and 500,000 fetal or newborn deaths each year worldwide.2

CercaTest RED is a patent-protected POCT (point-of-care test) for detection of misfolded proteins in urine samples to aid in the diagnosis and screening of pre-eclampsia after the 20th week of pregnancy. It is a non-invasive, easy to use one-step testing process with qualitative results within 5 minutes. CercaTest RED has been tested with nearly 3000 samples in 5 different clinical studies conducted in hospitals in the UK and China, where good performance in the diagnosis and short-term prediction of pre-eclampsia was observed. CercaTest Red will be marketed outside of China by Cerca Biotech GmbH, the German subsidiary of Shuwen Biotech.

"We are very pleased to have received the NMPA approval for dual uses. Our vision is for the use of CercaTest Red during clinic visits by Healthcare Professionals, and by patients in their own homes. As such, CercaTest Red may support effective detection and screening of Pre-eclampsia outside of the traditional clinic setting and in between appointments." commented Jay Z. Zhang, Executive Chairman and CEO of Shuwen Biotech, "As onset and aggravation of pre-eclampsia may be sudden and unpredictable, continuous and remote testing could save lives especially in those at high risk or with suspected pre-eclampsia."

About Shuwen Biotech
Shuwen Biotech is an integrated diagnostic 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 offered on the international market through Cerca Biotech GmbH (www.cercabiotech.com), Shuwen's European subsidiary in Berlin.

For more information
Visit the company website at www.shuwendx.com, or contact Jay Z. Zhang, info@shuwendx.com

1. National Medical Products Administration (nmpa.gov.cn)
2. Dimitriadis E. et al., Pre-eclampsia. Nature Reviews Disease Primers. (2023)9:(8).

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