ASX ANNOUNCEMENT **17 February 2020**

HeraBEAT Plus Clinical Trial Study Details

Medical technology company, **HeraMED Limited (ASX:HMD)** ("HeraMED" or the "Company") is pleased to provide additional details about its upcoming clinical trial with the Mayo Clinic, following previous announcement on 10 February 2020 titled "Mayo Clinic clinical study to evaluate HeraBEAT Plus".

The trial will progress over the coming months and will recruit low risk expectant mothers from the Mayo Clinic's Obstetrics and Gynaecology Department in Rochester, Minnesota. The trial will be led by Principal Investigator Yvonne S Butler Tobah MD, Consultant to the Department of Obstetrics and Gynaecology and head of Mayo's OB Nest program and co-investigators Regan Theiler MD, PhD, Chair, Division of Obstetrics, Department of Obstetrics and Gynaecology and Abimbola Famuyide MBBS, Chair of the Department of Obstetrics and Gynaecology. Mayo Clinic will use any revenue it receives to support its not-for-profit mission in patient care, education and research.

The overall study will encompass an assessment of the solution's functionality and user acceptability, as well as an evaluation of the impact of the device on the expectant mothers' perception of foetal wellbeing, measured by standardised surveys.

The HeraBEAT uses a smartphone-based interface, with real-time instructions for expectant mothers for determining both foetal heart rate (FHR) and maternal heart rate (MHR). The solution further includes a platform, which enables the measurements to be shared in a secure, confidential, and HIPAA (Health Insurance Portability and Accountability Act) compliant manner with the healthcare provider, to ensure proper support for the pregnant women using the device at home with medical supervision, analysis, and advice.

More specifically, the study will initially recruit 50 participants, with the potential for expansion and the primary goals are to outline:

1. Device ease of use - Measured using the self-reported System Usability Scale (SUS) on a scale from 1 to 5.
2. Foetal Heart Rate detection - Number of subjects to detect a foetal heart rate accurately using the device.

Study Type:	Interventional (Clinical Trial)
Estimated Enrollment:	50 participants
Allocation:	Randomized
Intervention Model:	Crossover Assignment
Intervention Model Description:	After approximately 8 weeks of monitoring, patients will complete an ease of use survey, then crossover to the alternate study product.
Masking:	None (Open Label)
Primary Purpose:	Diagnostic
Official Title:	Feasibility and Acceptability of a Medical Grade, Smartphone-based, Fetal Heart Rate Monitor for Outpatient Use: the **HeraBEAT™** Clinical Trial
Study Start Date :	February 1, 2020
Latest Study Close Date:	March 1, 2021

Criteria

Inclusion Criteria:

- At least 18 years of age
- Able to speak, read and understand English
- Able to provide informed consent
- Owns a suitable iOS or Android device and demonstrates average control and basic understanding of using a smartphone
- At least 12 weeks gestation
- Pregnancy documented as low risk

Exclusion Criteria:

- Any observed anomalies on first trimester dating or formal ultrasound
- Multifetal gestation
- Maternal history of defibrillation
- Maternal history of electro-surgery
- Patients with external electrical stimulators, cardiac pacemakers or requiring use of MRI or other high frequency medical equipment
- Clinical judgment that determines that the pregnancy is at high risk for complications
- Any of the following high risk factors would disqualify the mother for the study

For further details please visit –
https://clinicaltrials.gov/ct2/show/NCT04232215?titles=herabeat&draw=2&rank=1

This announcement has been approved by the Board of HeraMED Limited.

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About HeraMED Limited (ASX:HMD):

HeraMED is an innovative medical Data and Technology company leading the digital transformation of prenatal care. HeraMED utilises the digital health ecosystem including clinical home monitoring devices, cloud computing, artificial intelligence, big data and digital social networking to reshape the Doctor/Patient relationship. The Company is revolutionising the pregnancy experience by empowering personalised, continuous and proactive home monitoring, to deliver better care at a lower cost. Keeping pregnant mothers engaged, informed and well-supported provides reassurance and peace of mind while allowing the healthcare providers to work at their highest levels of ability and enabling early detection of potential risks.