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BP+ in Final Review Phase of NMPA in China

SYDNEY, Australia, Monday 29th March, 2021: Uscom Limited (ASX code: UCM) (the **Company** or **Uscom**) today notified the market that its novel hypertension and vascular assessment technology, the BP+ non-invasive central blood pressure monitor, has entered the final review phase of China National Medical Products Administration (NMPA) regulatory approval.

Supplementary materials were accepted by NMPA according to its regulators with all of the required product materials being currently reviewed by officers at the NMPA Center of Medical Device Evaluation prior to approval and issuance. Since the final submission on March 17th, Uscom has not received any requests for additional or revised BP+ materials from NMPA. The BP+ has already advanced through the documentation, drafting of test protocols, sample collection and testing, preparation of registration documents, NMPA review, and supplementary documentation and testing of samples phases of the regulatory process. The technical review will be completed within 60 working days, which will be followed by administrative approval and issuance within a further 30 days if the device complies with safety and efficacy requirements. Final NMPA approval is expected to by April to August, 2021.

The approval and sale of the BP+ in China will contribute an entirely new revenue stream from China, Uscom's biggest market.

The Uscom BP+ central blood pressure monitor provides information about the circulation and blood pressure previously only provided by invasive catheters, and is particularly specialised for hypertension and vascular health assessment. The BP+ technology is applicable across multiple hospital departments including ICU, Emergency, Cardiology, CCU, Obstetrics and ED's, etc.

Executive Chairman of Uscom, Associate Professor Rob Phillips said *"Hypertension occurs in approximately 1/3 of all adults (>1.13B adults worldwide) and is the leading modifiable risk factor for cardiovascular disease and death worldwide. In China more than 85% of patients with hypertension, ~230m adults, have ineffective diagnosis and control. Precise monitoring leads to improved therapy and outcomes, and the new BP+ is a technologic innovation in the hypertension and vascular assessment field. The NMPA approval of the BP+ is an important development for both Uscom and clinical care in China."*

The NMPA is the regulatory body that regulates medical device sales in China and is focused on determining the safety and efficacy of new technologies. Medical devices can only be sold in China following NMPA approval, a lengthy and complex administrative process. The BP+ has already received CE approval for sale into Europe, and is mid FDA process for the US market with approval expected in the next 6 months. The BP+ is installed in the international space station as an innovative technology for studying the changes in human blood pressure and pulse pressure waves in space.

References: Accessed 28th March
https://www.who.int/news-room/fact-sheets/detail/hypertension
https://www.who.int/china/health-topics/hypertension

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About Uscom

Uscom Limited (UCM): An ASX listed innovative medical technology company specialising in development and marketing of premium non-invasive cardiovascular and pulmonary medical devices. Uscom has a mission to demonstrate leadership in science and create noninvasive devices that assist clinicians improve clinical outcomes. Uscom has three practice leading suites of devices in the field of cardiac, vascular and pulmonary monitoring; the USCOM 1A advanced haemodynamic monitor, Uscom BP+ central blood pressure monitor, and the Uscom SpiroSonic digital ultrasonic spirometers. Uscom devices are premium resolution, noninvasive devices which deploy innovative and practice leading technologies approved or submitted for FDA, CE, CFDA and TGA regulatory approval and marketing into global distribution networks.

The USCOM 1A: A simple to use, cost-effective and non-invasive advanced haemodynamic monitor that measures cardiovascular function, detects irregularities and is used to guide treatment. The USCOM 1A device has major applications in Paediatrics, Emergency, Intensive Care Medicine and Anaesthesia, and is the device of choice for management of adult and paediatric sepsis, hypertension, heart failure and for the guidance of fluid, inotropes and vasoactive cardiovascular therapy.

The Uscom BP+: A supra-systolic oscillometric central blood pressure monitor which measures blood pressure and blood pressure waveforms at the heart, as well as in the arm, information only previously available using invasive cardiac catheterisation. The Uscom BP+ replaces conventional and more widespread sub-systolic blood pressure monitors, and is the emerging standard of care measurement in hypertension, heart failure and vascular health. The Uscom BP+ provides a highly accurate and repeatable measurement of central and brachial blood pressure and pulse pressure waveforms using a familiar upper arm cuff. The BP+ is simple to use and requires no complex training with applications in hypertension and pre-eclampsia, heart failure, intensive care, general practice and home care. The Uscom BP+ is supported by the proprietary **BP+ Reporter**, an innovative stand alone software solution that provides a digital platform to archive patient examinations and images, trend measure progress over time, analyse pulse pressure waves and generate summary reports.

Uscom SpiroSonic digital multi-path ultrasonic spirometers: High fidelity, digital, pulmonary function testing devices based on multi path ultrasound technology. They require no calibration, are simple to disinfect, and are simple and accurate to use providing research quality pulmonary function testing in small hand held devices that can be used in research, clinical and home care environments. The devices can be coupled with mobile phone apps and proprietary SpiroSonic software, **SpiroReporter**, with wireless interfacing to provide remote tele-monitoring of pulmonary disease. The devices are specialised for assessment of COPD, sleep disordered breathing, asthma, occupational lung disease and monitoring of pulmonary therapeutic compliance.

VENTITEST digital ultrasonic ventilator testing solution is a new system for testing ventilators. All ventilators require calibration to maintain the accuracy with which they measure the pressure, flow and volume of air they deliver. VENTITEST and VENTITEST-S, based on advanced SpiroSonic technology provides a testing solution that provides for simple and accurate testing, archiving, analysis and reporting to optimise ventilation performance.

For more information, please visit: www.uscom.com.au

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