LBT INNOVATIONS
ACN 107 670 673

MRSA ANALYSIS MODULE - CLINICAL STUDY COMMENCED

Adelaide, Australia, 2 April 2019: Australian medical technology company LBT Innovations Limited (ASX: LBT) (**LBT** or the **Company**), a leader in medical technology automation using artificial intelligence, announces the commencement of its clinical study to validate clinical performance of APAS® Independence's automatic analysis of Methicillin-resistant Staphylococcus aureus (**MRSA**). This extends the application of the APAS® Independence into surveillance of critical organisms for infection control, which offers additional utility of the instrument.

About MRSA and the Market Opportunity

Samples for the detection of MRSA are routinely and regularly conducted in many hospitals and other health care facilities. Testing for MRSA, along with Urine analysis, accounts for 50% to 70% of the culture plate volume in the target markets of Europe, the US and Australia. Therefore, the completion of MRSA modules will be a significant milestone for the Company. The addition of the MRSA modules, which is implemented for customers as a software update on the APAS® system, will further enhance the clinical utility of the APAS® Independence and provide increased sales opportunities.

The clinical study, being conducted in partnership with St Vincent's Hospital, Melbourne, represents the final stage in the development of the MRSA analysis modules. In an approach similar to the 10,000-patient clinical trial used for LBT's US FDA 510(k) de novo submission that was cleared by the FDA in 2016, APAS® results are compared against Microbiologists' interpretation. LBT have established blinded trial protocols to ensure the data integrity required to support intended regulatory filings and self-certification. This study provides evidence of clinical performance formally validating the modules before regulatory clearance can be achieved and the modules can be released to market. The Company is on track to have MRSA analysis modules available in the EU and Australia in the second half of 2019 under a self-certification process. The MRSA modules will be available in the US after FDA clearance is obtained.

The Company continues to improve its development of analysis modules through insourcing capability, process improvement and new partnerships with key opinion leaders. This has been a strategic focus of the Company over the past 15 months, to transition to a more efficient and scalable research and development process for analysis modules. In the case of MRSA, European reference site, Labor Dr Wisplinghoff in Cologne, Germany, supported the development of the module by capturing thousands of MRSA culture images using the APAS® Independence instrument. These images have been used to support the machine learning, software and algorithms development to create early versions of the final analysis modules. In addition, Labor Dr Wisplinghoff conducted performance testing of the modules and results have been accepted for presentation at the European Congress of Clinical Microbiology and Infectious Diseases (**ECCMID**) meeting which commences April 13th, 2019 and will be released to the market at that time.

Brent Barnes CEO and Managing Director said:

"The commencement of the MRSA clinical trial is another exciting development that will support the continued commercialisation of the APAS® technology by increasing the number of customers where the APAS® Independence provides clinical utility. It also signals LBT's transition from technology invention to a software manufacturing process for future analysis modules."

"I am also pleased to report that we have developed our own custom clinical trial platform to support the delivery of future clinical studies and ensure compliance with all regulatory requirements."

"Finally, I'd like to acknowledge the hard work of our analysis module development team and reference site partners. The milestone has been achieved through an industry leading collaboration between three different disciplines across microbiology, software development and artificial intelligence."

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About LBT Innovations

LBT Innovations (LBT) improves patient outcomes by making healthcare more efficient. Based in Adelaide, South Australia, the Company has a history of developing world leading products in microbiology automation. Its first product, MicroStreak®, was a global first in the automation of the culture plate streaking process. The Company's second product, the Automated Plate Assessment System (APAS®) is being commercialised through LBT's 50% owned joint venture company Clever Culture Systems AG (CCS) with Hettich Holding Beteiligungs- und Verwaltungs-GmbH. The APAS® instrument is based upon LBT's intelligent imaging and machine learning software and remains the only US FDA-cleared artificial intelligence technology for automated imaging, analysis and interpretation of culture plates following incubation.

CONTACTS

LBT Innovations	**Investor Enquiries**
Brent Barnes Chief Executive Officer & Managing Director Tel: +61 8 8227 1555 E: info@lbtinnovations.com	**David Allen / John Granger** Hawkesbury Partners Tel: +61 2 9103 9494 E: dallen@hawkesburypartners.com