

## VRE ANALYSIS MODULE - CLINICAL STUDY COMMENCED

Expanded suite of APAS® analysis modules for improved infection control

Adelaide, Australia, 19 March 2020: Australian medical technology company LBT Innovations Limited (ASX: LBT) (LBT or the Company), a leader in medical technology automation using artificial intelligence, is pleased to announce the commencement of its clinical study to validate the performance of the APAS® Independence Vancomycin-resistant Enterococcus, or VRE, analysis module. Once the clinical study is successfully complete, the VRE analysis module can be self-certified for commercial use in Australia and the European Union. This will then expand the number of tests customers can run on the APAS® Instrument and provide a second module for the surveillance of critical organisms in relation to infection control.

The VRE clinical study will be managed by LBT's clinical management team and supported by the Company's AI development laboratory in Adelaide. The study will compare the performance of the APAS® Independence with the VRE analysis module against the interpretation of three blinded microbiologists in the same way that was done for the urine and MRSA modules. This study will be the final stage in the development of the VRE analysis module, required to provide evidence of clinical performance and formal validation for regulatory clearance and release to the market. Following the clinical study, the Company will interpret the results and prepare relevant documentation and reports that are required to self-certify the clinical performance for release in the EU and Australian markets. The VRE module will be offered in the US once FDA clearance is obtained.

Once commercial, the VRE analysis module will be sold to customers as an additional annual licence fee to the urine and MRSA modules already available, which increases the revenue potential for each APAS® Independence. Customers will be able to access the module through a remote installation, similar to a software update on their APAS® instrument.

The clinical study will be completed using the Company's internal resources and will not impact current cash flow forecasts.

## About the APAS® VRE Analysis Module

Similar to Methicillin-resistant *Staphylococcus aureus*, or MRSA, VRE are antibiotic resistant bacteria routinely screened for by health facilities laboratories around the world. Specimens collected from "at risk" patients are sent to microbiology laboratories for testing and the results are critical to manage not only the care for that patient, but also the risk of infection spreading to other patients. Swift processing of VRE tests is critical to providing effective infection control within hospitals and protecting the spread of antibiotic resistant infections within the community.

The APAS® VRE analysis module automates the reading of VRE-culture plates and reports all negative results directly to the laboratory information management system. This is particularly important for infection control analysis modules, such as VRE or MRSA, as the tests typically have a high negativity rate of greater than 95%. The APAS® instrument is therefore able to provide crucial efficiency gains to laboratories for these high priority tests.

Brent Barnes CEO and Managing Director said:

"Commencing the VRE analysis module clinical study is another step forward for the APAS® technology by increasing the number of tests our customers can process using the APAS® instrument. Once complete, this will enable us to meet more of the needs of our customers and support future sales of the APAS® Independence."

"The work required to develop the VRE analysis module has been completed through our multi-disciplinary APAS® development team bringing together expertise in microbiology, software development and artificial intelligence."

Approved for release by the Chair of the LBT Board.



## **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

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