MRSA ANALYSIS MODULE CE MARK REGISTRATION

APAS® Independence with MRSA analysis module available for sale in the European Union

Adelaide, Australia, 25 September 2019: 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 that the Declaration of Conformity for the APAS® MRSA analysis module has been completed. This finalises the documentation required to make the MRSA analysis module available under the existing APAS® Independence CE Mark registration.

The Declaration of Conformity comes after the recent announcement that the MRSA analysis module clinical study was successfully completed, providing the validation required for regulatory clearance. The MRSA analysis module is now available for sale with the APAS® Independence in all member countries within the European Union.

MRSA Analysis Module Clinical Validation

The MRSA analysis module was completed in partnership with the Australian reference site, St Vincent's Hospital, Melbourne. This process required that results from the APAS® Independence were compared against a microbiologist's interpretation of the culture plates, demonstrating the instrument's ability to differentiate between culture plates demonstrating MRSA bacterial growth and those without. The APAS® Independence with MRSA analysis met the primary objective of the study, providing the clinical validation of the technology required for the CE Mark registration. The MRSA analysis module is now available to customers within the European Union.

The MRSA analysis module is particularly important for the launch of the APAS® Independence in the European Union where testing for MRSA is much higher than in other regions, due to greater requirements for infection control screening. In this market, MRSA testing combined with urine accounts for 50-70% of the specimens processed in the majority of laboratories. The high negativity rate of MRSA tests, which can be over 95%, makes it particularly well suited to the APAS® technology which automatically removes negative plates from the workflow, therefore providing greater value to our customers.

Outside of the European Union, the MRSA analysis module is also available for sale in Australia under the Company's existing TGA registration. In the United States the module will be made available after FDA clearance is obtained, with a FDA 510(k) submission for the MRSA analysis module is expected to be filed in the first quarter of 2020.

Future Analysis Module Development

The APAS® analysis modules are the artificial intelligence image analysis software at the heart of the APAS® Independence. Together with the APAS® instrument they form the technology that allows different clinical specimen types to be automatically screened using the APAS® Independence. A new analysis module is developed for each specimen type processed by microbiology laboratories. With the completion of the MRSA clinical study and CE Mark registration, the Company currently has analysis modules available to the market for urine culture plates and for MRSA infection control.

Each new analysis module for the APAS® instrument enables it to process more microbiology tests and therefore makes it more useful to our customers. LBT now plans to develop new analysis modules for infection control screening, such as for Vancomycin-resistant Enterococcus, and also target new applications such as antibiotic susceptibility testing. Additional work will include expanding the coverage of the urine analysis module to include the European Union.

Brent Barnes CEO and Managing Director said:

"Continuing to develop the APAS® technology through new analysis modules, such as the MRSA analysis module, is important for the Company as we continue with our commercialisation launch of the technology. Through this process we are able grow the number of microbiology tests we can support, enabling us to meet more customers' needs."

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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® Independence 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. The Company has regulatory cleared analysis modules able to support microbiology laboratories with the automated analysis of urine culture plates and for MRSA infection control.

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