US FDA 510(k) SUBMISSION FOR MRSA ANALYSIS MODULE

Expands the suite of APAS® analysis modules commercially available for US customers when approved

Adelaide, Australia, 30 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 submission of a 510(k) application to the United States Food and Drug Administration (**FDA**) for the APAS® Independence inclusive with the MRSA analysis module as a Class II medical device. FDA clearance is a necessary step required for the sale of this analysis module in the United States.

This FDA 510(k) submission for the APAS® Independence with MRSA analysis module uses the Company's previously cleared APAS® Independence device with Urine analysis module as a predicate device. The submission is supported by clinical data comparing the performance of the APAS® Independence against a reference panel of three clinical microbiologists across over 1,500 patients' specimens.

This important regulatory milestone in the United States, follows the CE Mark and TGA registration gained in September 2019 which then enabled commercial access to the European Union and Australia for the MRSA analysis module.

FDA Process and Expanding Market Access in the United States

The FDA has an established 510(k) submission process with a 90-calendar day review period following submission to the FDA. During this period the Company and the FDA can communicate as part of the detailed review process and as with previous submissions to the FDA, the Company expects to have a collaborative dialogue with the FDA. The Company notes that the 90-calendar day review process may stop at any time depending on the nature of the review questions and expects an outcome during the third quarter of calendar year 2020. This timeline may also be impacted by the COVID-19 global epidemic.

Subject to FDA clearance for the MRSA analysis module, the Company will have two analysis modules available for sale with its APAS® Independence in the United States. Together these two analysis modules can address approximately 50-70% of cultured specimens processed by the majority of laboratories in the United States. Each analysis module is sold as a separate software licence, enabling customers to customise the configuration of the APAS® Independence for their laboratory workflow and patient community. Additional analysis modules will increase the value proposition or clinical utility of the APAS® instrument for customers, by enabling a greater number of laboratories tests to be processed and increasing potential cost savings by automation. This is expected to increase return on investment for customers and expand the sales opportunity in the United States.

Brent Barnes CEO and Managing Director said:

"We are very pleased to submit this 510(k) application to the FDA and seek approval for our MRSA module which has already been approved in the European Union and Australian markets. I would like to recognise our clinical and regulatory teams for the hard work leveraging their experience from our two previous FDA submissions which have been approved. This has been a significant effort from all those involved.

We believe that expanding the number of analysis modules to our customers in each region is a critical part of our commercialisation strategy for the APAS® technology. Put simply, increasing the number of tests that can be processed on the APAS® instrument further increases the potential cost savings for our customers."

Approved for release by the Chair of the LBT Board.

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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: jgranger@hawkesburypartners.com