EUROPEAN UNION REGULATORY CERTIFICATION & MRSA STUDY RESULTS

APAS® Independence available for sale in European Union

Adelaide, Australia, 16 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 Conformité Européene or CE Mark self-certification has been completed for the APAS® Independence. CE Marking for the instrument enables the APAS® Independence to be sold in all member countries within the European Union.

The CE Mark registration has been completed to coincide with the completion of the clinical study for the MRSA analysis module. The APAS® Independence with associated MRSA analysis module successfully met the target sensitivity and specificity requirements of the study.

The timing of the CE Marking and MRSA analysis module clinical validation is in line with previous guidance for the third quarter of 2019.

MRSA Analysis Module Clinical Validation

The Company commenced the clinical validation of its MRSA analysis module in April 2019. The clinical study was conducted in partnership with the Australian reference site, St Vincent's Hospital, Melbourne, to compare the results from the APAS® Independence against a microbiologist's interpretation. The APAS® Independence with MRSA analysis module successfully met the sensitivity and specificity requirements, providing the clinical validation of the technology required for regulatory clearance. The analysis module will be made available for sale following finalisation of the documentation required to complete the Declaration of Conformity under the APAS® Independence CE Mark registration. This is expected to be finalised at the end of September 2019.

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. As such, 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 will be made 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. FDA 510(k) submission for the MRSA analysis module is expected in the first quarter of 2020.

European Commercial Update

The European Union is one of the largest microbiology markets, representing 35% of the global market. Within this market, CCS will initially target Germany and the UK, being the two largest microbiology markets in the region. These two countries collectively have an estimated 1,200 clinical laboratories, of which more than 350 are expected to meet the APAS® Independence target customer profile, by processing over 400 plates a day.

The Company has already commenced a sales and marketing campaign for the APAS® Independence ahead of regulatory clearance. In December 2018, a European Sales Executive was appointed with early efforts focussed on building market awareness through presentations at the annual European Congress of Clinical Microbiology and Infectious Diseases conference as well as lead generation via digital marketing and direct sales meetings with a number of high-volume laboratories.

Following these activities, over 130 potential laboratory customers have been identified with several laboratories expected to receive placements of an APAS® Independence, for performance evaluation prior to a potential purchase order. It is anticipated the conversion of these early sales opportunities will take time, as the sales process can require touchpoints with multiple stakeholders as well as a lengthy evaluation of the technology.

In line with our dual strategy for entry into global markets, the early commercialisation activities are focussed on generating interest in the product and building a sales pipeline ahead of potential distributor appointment in the EU region.

Brent Barnes CEO and Managing Director said:

"CE Marking for the APAS® Independence is an important step towards completing the Company's market launch strategy to have a regulatory cleared instrument available for sale in Australia, the EU and the USA. Furthermore, it provides our customers in the EU with a further technology validation and provides the catalyst to build on our sales activities in the region."

– ENDS –

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