UPDATE ON MRSA ANALYSIS MODULE US FDA SUBMISSION

Adelaide, Australia, 4 June 2020: Australian medical technology company LBT Innovations Limited (ASX: LBT) (**LBT** or the **Company**), a leader in medical technology automation using artificial intelligence, provides an update on the 510(k) submission to the United States Food and Drug Administration (**FDA**) for the APAS® Independence with MRSA analysis module.

Key Points

- **FDA feedback on 510(k) submission for MRSA module - requested clarification and additional information**
- **FDA submission will be on hold pending receipt of new information requested**
- **Response being diligently assessed and prepared to minimise expected delay in regulatory clearance from 3Q 2020**
- **No impact on existing regulatory clearances - FDA clearance of Urine analysis module and CE Mark of MRSA analysis module**
- **Current United States prospective sales opportunities not impacted**

FDA feedback and request for additional information

Following the application to the FDA for the APAS® Independence with MRSA analysis module on the 30 March 2020, the Company has now received notification from the FDA that its application is on hold pending the provision of additional information. The Company has taken the opportunity to attend a teleconference with the FDA to discuss the feedback. This was helpful to better understand the FDA's thinking and assist the Company to diligently prepare a comprehensive response to the FDA as soon as practicable.

The Company has 180-calendar days to provide a formal response or the FDA will consider the application withdrawn. The specific matters raised by the FDA are commercial in confidence and the Company expect to lodge a formal response with the FDA within the 180-calendar days provided.

It is important to note the issues raised by the FDA do not impact the existing FDA clearance for the APAS® Independence with Urine analysis module. As a result, the Company does not expect any impact to existing sales opportunities in 2020.

The matters raised by the FDA do not impact the availability of the MRSA analysis module in other regions, nor likely to impact the current discussions with distributors. The Company will therefore continue to work with customers in both Australia and the European Union to sell the technology with its CE Mark and TGA clearances. The MRSA analysis module is currently in routine use at the German reference site, Labor Dr Wisplinghoff.

LBT CEO and Managing Director, Brent Barnes said:

"We had a productive call with the FDA today and believe we will be able to address their issues and requests for additional information. At this stage the planning of our response is still a work in progress so we cannot accurately assess the likely timing to resubmit to the FDA."

Update on release of data from The Johns Hopkins Hospital independent evaluation

As previously announced, The Johns Hopkins Hospital completed an independent clinical evaluation of the performance of the APAS® Independence with MRSA analysis module. The data was scheduled to be published in June 2020 at the ASM Microbe Conference in Chicago, however this conference has been cancelled due to COVID-19. The Company confirms that the results of the independent evaluation were successful and met expectations. Furthermore, The Johns Hopkins Hospital has indicated they will independently publish the results later in 2020.

Approved for release by the Chair of the LBT Board.

– 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