APAS® INDEPENDENCE RECEIVES US FDA 510(k) CLEARANCE

Regulatory clearance of commercial instrument provides access to over 1,500 U.S. laboratories as potential customers

Investor call at 9.00am AEST, Tuesday 21 May 2019 to discuss FDA clearance and U.S. market opportunity

Adelaide, Australia, 20th May 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 its 50% owned joint venture company, Clever Culture Systems (**CCS**) has received 510(k) clearance from the United States Food and Drug Administration (**FDA**) for its APAS® Independence instrument with associated urine analysis module (**AM**).

The FDA clearance of this commercial instrument is the final regulatory milestone enabling commencement of sales of the APAS® Independence in the United States. The milestone has been achieved as part of a dedicated effort from the Company. LBT is not aware of any other competing products cleared by the FDA for similar applications, making the APAS® Independence the only commercially available instrument for the automatic reading of culture plates in the United States. This FDA approval now enables CCS to bring forward its US commercialisation and sales activities.

FDA 510(k) clearance as a Class II Medical Device

The APAS® Independence is a fully automated instrument with the ability to process over 200 culture plates per hour, which is at least three times faster than manual culture plate reading. The instrument is able to differentiate culture plates showing bacterial growth from those that are not, without the need for highly skilled microbiologist assistance. This is key to the clinical utility of the instrument that enables the instrument to be truly autonomous, and without the need for further intervention. As a result, the APAS® Independence is a Class II medical device.

This second FDA clearance is an extension of that achieved in October 2016 for the manual loading version, APAS® Compact. The first clearance was granted after a *de novo* submission to the FDA and completion of 10,000 patient global clinical trial conducted in the US and Australia. The 510(k) application for the APAS® Independence demonstrated the instrument to be substantially equivalent to the manual APAS® Compact instrument.

A comparison of APAS® Compact and the APAS® Independence is attached to this announcement along with updated guidance on the U.S. commercialisation pathway.

U.S. Market Opportunity

This FDA clearance for the APAS® Independence with urine AM represents a significant step forward in CCS's 2019 commercialisation plan as it enables commercial launch to begin in the United States. With over 5,000 clinical laboratories, the United States represents the single largest pathology market in the world. The Company estimates that there are more than 1,500 laboratories that exceed the daily culture plate volume that would make the commercial return on investment for the purchase of an APAS® Independence attractive.

With this FDA clearance, CCS will now ramp up its commercial activities in the United States with sales lead generation activities having already begun. Building from the Company's experience in the Australian market and with a better understanding of lead time for sales, CCS has already reached out to over 800 laboratory stakeholders in the United States. To date, interest from potential customers has been positive and CCS expects to commence customer evaluations before the end of 2019, targeted to customers that have a near term intent to procure an APAS® Independence.

In June 2019, CCS will be at the American Society of Microbiology (**ASM**) Microbe meeting being held in San Francisco. As part of ASM Microbe, LBT's key opinion leader Dr Glen Hansen (Hennepin Healthcare System, Minneapolis), will be presenting data from his laboratory using the APAS® Independence, titled:

"Intelligent automation - The first US use of the APAS® Independence delivering artificial intelligence for clinical microbiology automation".

After ASM Microbe, CCS will be also attending regional ASM meetings across the country to increase customer awareness of the APAS® Independence and drive the growth of the sales pipeline. CCS's reference site at Hennepin Healthcare System will also host a number of customer demonstrations showcasing the APAS® Independence in use in a clinical setting. The purpose is to build strong regional demand for the instrument ahead of targeted distributor placement.

Brent Barnes CEO and Managing Director said:

"The FDA clearance for the APAS® Independence is a hugely exciting development as it secures LBT's first mover advantage with the only FDA cleared Class II commercial product of its kind available for sale in the United States. The focus now is on ramping up commercialisation activities in the region to convert interest into early sales."

Investor Conference Call

The Company will hold a conference call at **9.00am AEST on Tuesday 21 May 2019** to discuss the FDA 510(k) clearance, updated US commercialisation plans and what it means for the Company's market access in the United States. The Company's CEO and Managing Director, Brent Barnes, will host the call.

To dial into the call directly, please dial in 5 to 10 minutes prior to the call time and enter the **Conference ID: 10000499**. Dial in numbers are as follows:

Australian Toll Free:	**1800 908 299**
New Zealand callers:	0800 452 795
Other callers:	+61 2 9007 8048

To pre-register for the call, please follow the link below. A unique pin number will be provided for use when dialling into the call, which will bypass the operator and provide immediate access to the event.

https://services.choruscall.com.au/diamondpass/lbt-10000499-invite.html

A recording of the call will be available on the Investor Centre section of the Company's website for 60 days after the call.

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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

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APAS® FDA Pathway

FDA *de novo* clearance
Oct-2016

Manual loading
(prove technology)

APAS® - first AI for culture plate reading

APAS® Compact

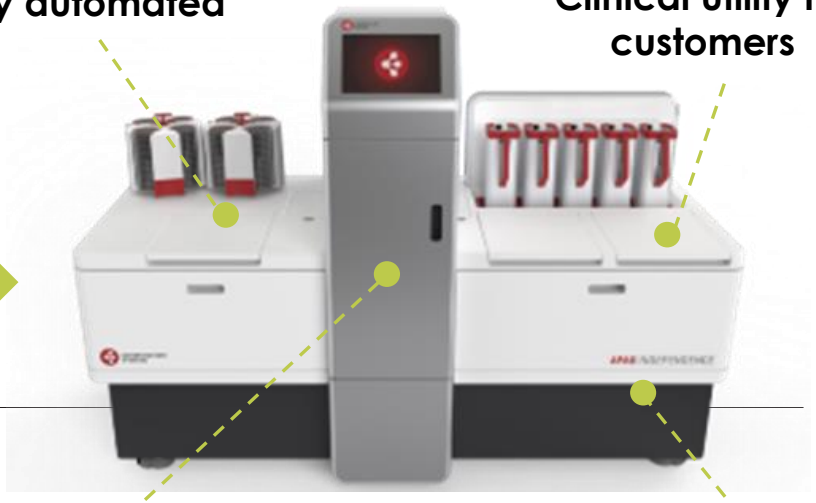
10,000-patient clinical trial

Class II medical device

FDA 510(k) clearance
May-2019

Fully automated

Clinical utility for customers



APAS® Independence

Equivalent to APAS® Compact

Class II medical device

Validation of technology

Available for sale in the US

US commercialisation pathway

APAS Independence cleared for sale in the United States