LBT INNOVATIONS
ACN 107 670 673

US FDA 510(k) SUBMITTED FOR APAS® INDEPENDENCE

Key milestone to ensure US commercial launch and sales pipeline in 2019

Adelaide, Australia, 21 December 2018: 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 50% owned joint venture company, Clever Culture Systems (**CCS**) has filed a 510(k) application with the United States Food and Drug Administration (**FDA**) for its APAS® Independence instrument with associated Urine Analysis Module.

This important milestone for the Company supports the expected commercial launch of the APAS® Independence instrument in the United States in 2019. Obtaining FDA clearance for the APAS® Independence instrument facilitates commercial market access and the ability for sales to commence in the single largest pathology market globally. This submission follows the recent placement of the first APAS® Independence instrument in the United States (for investigational use) into Hennepin Healthcare System, a laboratory in Minneapolis. It is expected that a number of initiatives targeting early market awareness will occur during 2019 calendar year to build up the early sales pipeline in the US.

FDA de novo achievement for APAS®

A de novo application is required when there is no existing predicate device cleared by the FDA. In October 2016, CCS received a clearance for its 510(k) de novo submission, which the FDA cleared for APAS® as a Class II medical device. The de novo submission used a manual version of APAS® to test 10,000 patients in a series of clinical trials conducted in the US and Australia over a 12-month period. This achievement demonstrated the core artificial intelligence and imaging capability of APAS®, de-risked the regulatory path to market and was a global first.

FDA 510(k) for APAS® Independence

A 510(k) submission requires new devices to be comparable or substantially equivalent to existing predicate device(s) already previously cleared by the FDA. CCS is the originator for the predicate device of APAS® and has access to the complete data on both the APAS® manual loading instrument and the fully automated APAS® Independence instrument, representing an expected straight forward path for 510(k) review. The Company is not aware of any competing 510(k) submissions against its predicate, once again making this a global first.

Timing

The FDA has a very clear and transparent 510(k) submission process. Once the 510(k) is submitted, there is a 90-calendar day review process. There are a number of opportunities for the Company and the FDA to communicate as part of the detailed review process, and during this time the 90-calendar day process may or may not stop depending on the nature of the review questions. The Company expects to have a collaborative dialogue and set of questions and answers with the FDA as it did during the de novo application.

LBT CEO and Managing Director, Brent Barnes, said:

"*The preparation of the submission milestone is a culmination of years of development work on both the physical instrument development as well as the AI platform. I'd like to acknowledge the hard work of our team and partners in putting together a comprehensive dossier. Approval enables CCS to market the APAS® Independence in 2019. We understand the typically long sales cycles for capital equipment. This is why in parallel to our regulatory process, we have established a centre of excellence reference site and expect to have a presence at a number of US based conferences to build awareness leading up to the FDA decision. We continue to strive to have the APAS® Independence instrument to be the first FDA cleared Class II commercial product of its kind available for sale in the US during 2019.*"

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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. LBT's third product WoundVue® is in early development; this is a proposed automated solution to assist in the management of chronic wounds.

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