



ASX/MEDIA RELEASE

The Manager
Company Announcements Office
ASX Limited

US FDA GRANTS APPROVAL FOR LBT'S APAS®

- FDA clears APAS® imaging and software technology as a Class II medical device

ADELAIDE, Australia, 10th October, 2016: Clever Culture Systems AG (CCS), the Swiss based joint venture between Australian medical technology company LBT Innovations Limited (ASX: LBT) and Hettich AG (Switzerland) has received clearance of its 510(k) *de novo* submission to the US Food and Drug Administration (FDA) for APAS® as a Class II medical device.

APAS® (Automated Plate Assessment System) is a breakthrough artificial intelligence technology for the automated imaging, image analysis, interpretation and reporting of growth on microbiology culture plates after incubation. APAS® enables the faster diagnosis and reporting of infectious diseases.

Developed by LBT Innovations, APAS® has been licensed on a global, exclusive basis to CCS, which is integrating APAS with laboratory robotic instrumentation. CCS is targeting to bring APAS to market in 2017 as an automated stand-alone plate reader (APAS® Independence) followed by the integrated incubator (APAS® Incubot).

The 510(k) *de novo* submission used a manual version of APAS to test 10,000 patients in a series of clinical trials conducted in Australia and the US over a 12-month period. In each trial, APAS achieved its target primary endpoints and the results matched or exceeded the findings of a panel of experienced microbiologists.

Mr Brent Barnes, CEO of LBT Innovations, said, "FDA clearance follows rigorous interrogation and validation of the capabilities of APAS. The successful clinical trial program completed in 2015 and clearance by FDA also validate the underlying technology that is the core platform of our Company's vision to integrate imaging with interpretative intelligence to deliver faster and more secure diagnoses for patients. FDA clearance is a fitting tribute to the many years of painstaking work by LBT's staff and partners, who together have made our shared vision a reality."

Mrs Lusia Guthrie (recently retired LBT CEO and Chairman of CCS), confirmed that CCS is in continuing discussions with significant global diagnostics companies for the licensing of the APAS product portfolio, including APAS Independence and APAS Incubot, plus flow-on product opportunities on the drawing board all aimed at the clinical microbiology laboratory.

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About LBT Innovations

LBT Innovations (LBT) is an Australian developer of clinical and diagnostic technology. Based in Adelaide, South Australia, the Company has two class-leading products in microbiology automation: MicroStreak®, which provides automated culture plate streaking and APAS®. Based on LBT's innovative intelligent image interpretative platform, APAS® specifically addresses the automated imaging, analysis and interpretation of culture plates following incubation. LBT has entered into a joint venture Clever Culture Systems AG (CCS) with Hettich AG Switzerland to drive the commercialisation of APAS® products. LBT also has a third product in early development, WoundVue®, a proposed automated solution to assist in the management of chronic wounds.

For more information, see www.lbtinnovations.com



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