FIRST APAS® PHARMAQC PERFORMANCE DATA FROM ASTRAZENECA INSTALLATION

APAS® PharmaQC demonstrates 100% sensitivity for microbial growth detection

Adelaide, Australia, 10 August 2023: Australian medical technology company LBT Innovations Limited (ASX: LBT) (**LBT** or the **Company**), a leader in microbiology automation using artificial intelligence, is pleased to report preliminary performance data for its APAS® PharmaQC product automated reading of environmental monitoring culture plates, indicating a 100% sensitivity was achieved for microbial growth detection, demonstrating the required performance for this stage in the development project.

Key Points:

- **Data collected from AstraZeneca's routine environmental monitoring processes**
- **A total of 1,515 environmental monitoring plates assessed during the study**
- **The study compared APAS® PharmaQC versus human reading for microbial growth detection**
- **APAS® PharmaQC demonstrated 100% sensitivity for microbial growth detection**

As part of Company's ongoing product development program with AstraZeneca, an initial assessment of the APAS® PharmaQC product performance was completed, comparing the APAS® PharmaQC screening result with human reading for microbial growth detection. The study comprised 1,515 environmental monitoring plates, with the majority of plates (1,477) collected from AstraZeneca's routine environmental monitoring processes. Given the low number of plates with microbial growth in cleanrooms, an additional 38 plates were added to the study to increase the number of positive plates and test the accuracy of APAS® PharmaQC growth detection. This study is the first formal assessment of the performance of APAS® PharmaQC completed using real-world environmental monitoring data from industry.

A summary of APAS® PharmaQC results:

- 100% sensitivity for microbial growth detection. This means APAS® PharmaQC detected all plates that contained growth correctly
- 91.7% of plates were correctly removed from the manual workflow (1,390 negative plates / 1,515 total plates)
- 7.3% of plates reported by APAS® PharmaQC as positive, where the actual result was negative (false positive)
- 1 plate classified as having no-growth (negative) by manual reading was correctly classified by APAS® PharmaQC as has having growth (positive)

The overall performance of the APAS® PharmaQC product has met the requirements for this stage of the project. The next steps of the project are to complete pilot validation testing assessing a broader range of performance metrics as defined by pharmacopeial requirements, before a formal validation program will be executed by both LBT and AstraZeneca. It is expected that the formal validation program will commence in the fourth Quarter of calendar year 2023, supporting the planned product launch in the first half of calendar year 2024.

A summary of the results is attached with this announcement.

The pharmaceutical market is the second of two commercial channels for LBT, following the Company's already established products for clinical laboratories. The APAS® PharmaQC application for reading of environmental monitoring culture plates, offers substantial benefits for pharmaceutical customers, driving process efficiency and quality enhancements. The Company see a large market opportunity for the APAS® technology in the pharmaceutical market, and a motivated customer base looking for scalable solutions that deliver production process improvements.

LBT Research Director, Mr Rhys Hill added:

"These results are hugely encouraging and give us confidence that we are on track with our currently development objectives. Ensuring the system does not miss any potential growth on the plate is incredibly important for the application as any microbial

growth within a sterile manufacturing facility can be a cause for investigation. We therefore tune the system to be conservative ensuring no positive plates are missed. The fact that we were able to achieve 100% sensitivity for microbial growth detection is therefore really important."

Approved for release by the Chair of the LBT Board.

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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 culture plate specimen processing. The Company's second product, the Automated Plate Assessment System (APAS® Independence) uses LBT's intelligent imaging and machine learning software to automate the imaging, analysis and interpretation of culture plates following incubation. The technology remains the only US FDA-cleared artificial intelligence technology for automated culture plate reading and is being commercialised through LBT's wholly owned subsidiary Clever Culture Systems AG (CCS). Thermo Fisher Scientific, Inc is exclusive distributor of the APAS® Independence in the United States and selected countries in Europe.

INVESTOR ENQUIRIES

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Pilot Secondary Validation Study

Total 1,515 environmental monitoring plates collected during routine production at AstraZeneca facility

- 1,477 Environmental monitoring plates collected from Class A cleanroom (including settle and finger dab plates)

- 38 contrived plates (11 pos, 27 neg) collected to increase positivity rate

- Data collected from LIMS system to provide reference result for each plate

Plates subsequently run through APAS Independence to assess performance using "real-world" data and identify any discrepant results between human and AI

- Measured growth vs no growth performance

Summary of Performance

APAS® PharmaQC demonstrates 100% sensitivity for microbial growth detection

Discrepant analysis investigations:

- APAS identified potential additional positive plate(s) missed by normal reading

- Top causes of disagreement between reference count and APAS:
  - Tape applied to plates during processing
  - Labels incorrectly applied to plates
  - Excessive text markings on the plate
  - Product identified on the plate

Results:

AZ	APAS			
		No growth	Growth	Total
	No growth	1390	110	1500
	Growth	0	15	15
	Total	1264	251	1515

- Positive percent agreement (PPA): 100% (15/15 correct)

- False negative rate (FNR): 0% (0/15 incorrect)

- Negative percent agreement (NPA): 92.6% (1390/1500 correct)

- False positive rate (FPR): 7.3% (110/1500 incorrect)