APAS® PHARMAQC COMMERCIALLY READY – PERFORMANCE FINALISED

Primary validation data delivers evidence and credibility for the technology

Adelaide, Australia, 13 March 2024: Australian medical technology company LBT Innovations Limited (ASX: LBT) (**LBT** or the **Company**), a leader in microbiology automation using artificial intelligence, is pleased to announce the successful completion of primary validation for the APAS® PharmaQC product. The completion of the milestone represents the final step in the product development and technology commercialisation.

Highlights:

- **APAS® PharmaQC technology commercially ready – formal release to AstraZeneca**
- **Primary validation testing and final research & development completed:**
  - **Completed to pharmacopeial requirements[1] confirming APAS® PharmaQC as an alternative method**
  - **Significant data generated with over 35,000 plate images captured**
  - **APAS® PharmaQC successfully meets all performance targets**
- **Validation a critical step in building commercial opportunities with prospective customers**

Commercial importance

Culture plate reading and reporting during environmental monitoring is a critical step for pharmaceutical manufacturers to release drug products. Improving quality control, traceability and data integrity of results is important in pharmaceutical manufacturing. It is common practice in the pharmaceutical industry for prospective customers to request primary validation performance data.

The successful primary validation of APAS® PharmaQC establishes a significant body of evidence that assesses the performance of the product against pharmacopeial requirements as an alternative microbiology method. Completing primary validation builds credibility and confidence in the APAS® PharmaQC technology. There are no additional regulatory clearances, licenses or authorities that are required to approve the product. The technology is now commercially ready and available for sale globally.

The completion of primary validation and formal release of the product finalises the development project with AstraZeneca Plc (**AstraZeneca**). AstraZeneca will now undertake an internal secondary validation of the system within its own manufacturing processes. Completion of AstraZeneca's secondary validation is anticipated in the third quarter of calendar year 2024.

Brent Barnes, CEO & Managing Director said:

"Evidence based automation is incredibly important in the biopharmaceutical industry. The completion of our primary validation is a valuable asset to the Company. We expect this data to build confidence in our technology and assist customers with their adoption of APAS® PharmaQC.

Many customers we've spoken to over the past 6 months gave positive feedback on our technological approach and we are looking forward to sharing our primary validation data with them. We have set ourselves an ambitious commercialisation schedule for 2024 and expect the customer qualification pipeline to accelerate as we present our APAS® PharmaQC technology at a number of key global conferences.

Summary of results

The Company's primary validation program was designed to meet the pharmacopeial requirements for the validation of alternative microbiology methods used in pharmaceutical manufacturing. These requirements define various tests that assess the performance of the technology to the current compendial method. In this case manual reading of the culture plates by

[1] Validation requirements informed using USP<1223>, Ph Eur 5.1.6, USP<61> and Ph Eur 2.6.12.

two microbiologists is the existing method. The data generated in the study establishes a key body of evidence required by customers when seeking to adopt the technology.

Highlights from the study:

- Over 35,000 plate images captured, 40,000 microbiologist plate reads and approximately 3 million colonies counted
- 9 microbial organisms tested across a broad range of operational conditions and practices
- All performance targets for the technology successfully achieved:
  - **Primary performance target:** 0% Qualitative False Negative Rate - *No plates with microbial growth missed by APAS® PharmaQC during testing*
  - **Secondary performance target:** High counting accuracy and linearity demonstrated for standard organisms

Approved for release by the Chair of the LBT Board.

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About LBT Innovations

LBT Innovations (LBT) provides intelligent automation solutions to microbiology laboratories. Based in Adelaide, South Australia, the Company has developed a best-in-class technology, the Automated Plate Assessment System (APAS® Independence), using artificial intelligence and machine learning software to automate the imaging, analysis and interpretation of microbiology culture plates. 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). The product is currently being sold to microbiology laboratories in the pharmaceutical manufacturing sector for the reading of environmental monitoring culture plates and to clinical laboratories as an in vitro diagnostic for infectious diseases. Thermo Fisher Scientific, Inc is exclusive distributor of the APAS® Independence to clinical customers in the United States and selected countries in Europe.

INVESTOR ENQUIRIES

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