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ECHO IQ ADVANCES GLOBAL REGULATORY COMPLIANCE STRATEGY

Highlights:

- **Completion of US Reader Study patient enrolment for FDA 510(k) application and commencement of Study**
- **Defined strategy to obtain New Technology Add-On Payment (NTAP) certification in the event of successful FDA clearance**

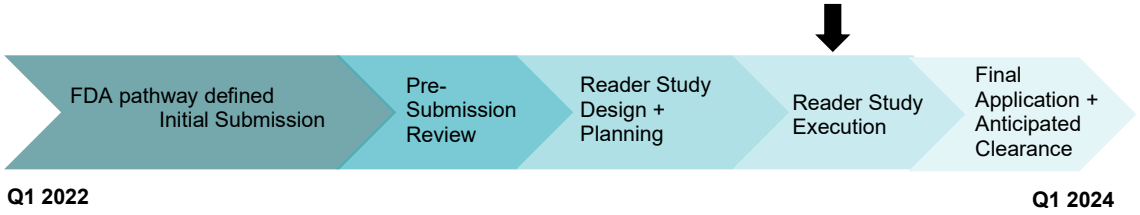
Sydney: Artificial Intelligence and Medical Technology company Echo IQ ("the Company") (ASX:EIQ) is pleased to announce a number of significant advancements in its stated strategy to establish a clear pathway to regulatory compliance in its priority target markets.

US Reader Study Progress

As previously announced (*refer ASX Announcement 28 April 2023*) Echo IQ is conducting a Reader Study in the US to assess diagnostic accuracy and clinical performance for its EchoSolv™ technology in support of its application for FDA clearance. The Company advises that enrolment of the patient (studies) and clinical readers for the study has been fully completed and the study has now commenced.

This study, being conducted in a US hospital, is expected to form part of the Company's final FDA 510(k) application. The study protocols have been developed to comply with the FDA's routine evaluation of clinical decision support software. This approach uses MRMC (Multiple Reader, Multiple Case) studies for computer-assisted diagnosis devices and aims to evaluate the performance and effectiveness of such systems. Completion of the reader study is expected to take approximately 80 days, following which Echo IQ expects to submit its final FDA 510(k) application. The FDA currently publicises its timeframe for decision response as being a further 90 days from lodgement of final application.

FDA 510(k) Application Timeline



NTAP Strategy Defined

On successful achievement of FDA clearance, the Company has prioritised seeking to obtain New Technology Add-On Payment (NTAP) designation from the US Centers for Medicare and Medicaid Services (CMS).

NTAP designation would permit customers of EchoSolv™ to obtain reimbursement of usage costs, to a defined limit of the lesser of 60% of the cost of the underlying service or US$1040, and would be expected to accelerate wide-spread usage of the solution in hospital environments.

The Company's advisors have indicated that EchoSolv™ meets the key criteria for NTAP, being:

- Novelty;
- Cost-effectiveness; and
- Substantial clinical improvement.

Moreover, EchoSolv™ specifically supports improved diagnosis of conditions where the failure to accurately diagnose can result in death.

Comments

Echo IQ Executive Chair Andrew Grover said: "*Initial commercial uptake of EchoSolv™ has commenced and we continue to advance engagement with leaders in the valve, pharma, hardware and software and reporting sectors. The important steps towards US regulatory clearance we are announcing, along with the decision to prioritise NTAP designation, support both the roll-out of our fully AI-enabled suite of solutions for aortic stenosis, and increase the speed with which we can deploy EchoSolv™ in a large range of healthcare facilities. Echo IQ remains focused on delivering a solution that is robust, effective and meets the needs of the cardiology community in a manner that is tested, safe and recognised by leading regulators internationally.*"

- ENDS -

Authorised for release by the Board of Directors of Echo IQ Limited.

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ABOUT ECHO IQ
Echo IQ uses AI-driven technology and proprietary software to improve decision making in Cardiology. The company is based in Sydney, Australia.