ASX: EIQ RELEASE **7 MAY 2024**

FORMAL SUBMISSION LODGED WITH US FDA FOR AI-SUPPORTED ECHOSOLV-AS SOLUTION

Highlights:

- **EchoSolv™ is a decision support tool which assists in the detection of structural heart disease**
- **FDA application seeks market clearance for the use of EchoSolv-AS in AI-mode to assist in the diagnosis of aortic stenosis**
- **Application is submitted under 510(k) expedited process – standard decision timeframes published by FDA as being 90 days**
- **Submission follows positive engagement with the FDA during pre-submission meetings and includes supporting data from recently completed US reader study**
- **Clearance is expected to significantly accelerate commercial uptake**
- **Multiple US healthcare groups have indicated that FDA clearance is an important step in their decision-making process prior to potential commercial arrangements**
- **Appointment of expert advisors to secure US insurance reimbursement codes**

Sydney: Artificial Intelligence and Medical Technology company Echo IQ ("the Company") (ASX:EIQ) is pleased to advise that it has formally submitted its full and complete US Food and Drug Administration ("FDA") application for market clearance of its proprietary artificial intelligence ("AI") backed decision support tool to assist in the detection of aortic stenosis ("EchoSolv™ AS"). EchoSolv™'s novel machine learning algorithm was developed by the Company using access to cardiac data covering millions of echocardiographic data points.

According to FDA guidelines, applicants under the 510(k) expedited process can anticipate a decision regarding clearance 90 days from the date of submission. Assuming no requests for additional information are issued by the FDA, Echo IQ could receive clearance to market early in August 2024.

The Company's application has been developed over the last 12 months and follows a positive pre-submission meeting with the FDA and the completion of a US Reader Study to exemplify clinical performance (refer ASX announcement: 27 March 2024).

Securing FDA clearance would provide a significant catalyst for the deployment of the Company's AI-backed product in the US and allow cardiologists to integrate the solution into current clinical workflows. In turn, this is expected to significantly broaden the addressable market allowing cardiologist groups and hospitals to generate additional revenue from insurance providers and public health rebate channels.

A number of large US healthcare groups have indicated that FDA clearance would mark an important step in their consideration for deployment of the technology, and the Company anticipates that a positive response by the FDA will lead to increased commercial uptake.

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The Company has also appointed a leading US consultancy to support the obtainment of reimbursement codes for users of Echo IQ's cutting-edge technology under insurance. This will create financial incentives for more widespread use of EchoSolv™ in US hospital settings.

Executive Chairman, Mr Andrew Grover said: *"The Company's FDA submission marks a major milestone in its regulatory compliance strategy and concludes an extensive period of clinical studies highlighting the solution's potential. We are confident that clearance from the regulator, which is expected in 90 days, will unlock a significant opportunity for commercial deployment. Our team has nurtured a robust pipeline of potential customers, laying the groundwork for future growth and success."*

- 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.