ASX: EIQ RELEASE **24 November 2025**

Validation study for EchoSolv HF completed at the Mayo Clinic – Study delivers exceptional results

- **Clinical validation successfully completed with Mayo Clinic Platform's Validate program – marking the final clinical requirement prior to FDA 510(k) submission**
- **EchoSolv HF validation met the primary endpoint, delivering performance exceeding company expectations in detecting heart failure on an independent dataset**
- **Study was undertaken across 17,000 individual patient echocardiograms from the Mayo Clinic Platform with results highlighting:**
  - **Sensitivity of 99.5%, accurately identifying true positives**
  - **Specificity of 91.0%, detecting true negatives**
- **FDA 510(k) submission now being finalised with lodgement expected in the coming weeks**
- **Company to leverage existing footprint in the US market to drive uptake of EchoSolv HF post potential FDA clearance**
- **FDA clearance of EchoSolv HF would unlock a major market opportunity in the US:**
  - **Only 50% of heart failure cases are accurately diagnosed**
  - **Heart failure is the leading cause of rehospitalisation and accounts for 17% of US healthcare expenditure**
  - **Total addressable market in the US is US$60Bn**
  - **Estimated that 1 in 4 Americans will develop heart failure in their lifetime**
- **Webinar scheduled for Wednesday, 26 November at 11:00am (AEDT)**

Sydney: AI and Medical Technology Company Echo IQ Limited (ASX: EIQ) ("Echo IQ" or "the Company") is pleased to advise that it has completed its clinical validation for its heart failure clinical decision support software ("EchoSolv HF") in collaboration with the Mayo Clinic Platform ("MCP"), a division of the Mayo Clinic, a top ranked US hospital. The MCP Validate program is a unique in-market AI evaluation program which generates an independent and objective report on accuracy, efficacy and susceptibility to bias for AI-based decision software (refer ASX Announcement 1 July 2025).

The clinical validation was designed to evaluate the EchoSolv HF model's ability to detect heart failure on an independent dataset of ~17,000 individual echocardiogram studies. In a major milestone, the primary endpoint of the clinical validation has been met, with results exceeding expectations.

The study results show that EchoSolv HF demonstrated outstanding performance in identifying patients with heart failure, **achieving a sensitivity of 99.5%.** Likewise, the model was accurate in identifying patient that did not have heart failure, **achieving a specificity of 91.0%.**

Completion of the clinical validation marks the final clinical requirement prior to a formal submission for clearance by the US Food & Drug Administration ("FDA").

Echo IQ is now in the process of completing its formal submission to advance the clearance of EchoSolv HF via the FDA's 510(k) regulatory pathway. The Company expects to lodge this submission in the coming weeks.

FDA clearance of the solution would allow for EchoSolv HF to be marketed to and used by healthcare professionals in the USA as a clinical decision support software to aid in the detection of heart failure.

Heart failure is the leading cause for rehospitalisation in the US and accounts for 17% of all healthcare expenditure in the country[i]. It has a total market size of US$60Bn[ii], which is expected to grow due to the under-utilisation of evidence-based support tools like EchoSolv HF and rising mortality rates. It is now estimated that one in four Americans will develop heart failure in their lifetime[iii].

Upon potential FDA clearance of the solution, the Company intends to leverage its existing footprint in the US market to drive uptake of EchoSolv HF.

Webinar:

Echo IQ will host a webinar at 11:00am AEDT on Wednesday, 26 November 2025 during which CEO, Mr Dustin Haines will provide an overview of this development. Recently appointed US Head of Commercial, Mr Nick Lubbers will also present an update to investors on the Company's progress in the US market. The briefing will be followed by a Q&A Session. Questions can be submitted now to investors@echoiq.ai.

Anyone wishing to attend the webinar must register in advance, using the link below:

Date and time: 11:00am AEDT (8:00am AWST) on Wednesday, 26 November 2025

Register via: https://us02web.zoom.us/webinar/register/WN_PlLK4Ch4Say6Ahv_cDukqw#/registration

Management commentary:

Chief Executive Officer, Mr Dustin Haines, said: *"Completion of this clinical validation study represents a major milestone in the commercialisation of EchoSolv HF. The independent confirmation of our model's accuracy and reliability through the Mayo Clinic Platform's Validate program have exceeded internal expectations and provides strong objective evidence supporting the clinical utility of EchoSolv HF in real-world settings, particularly compared to existing diagnostic tools being utilised across the US. This clinical validation sets Echo IQ on a path to deliver category leading evidence for supporting clinicians in diagnosing heart failure accurately, earlier and more confidently."*

With this final clinical requirement now complete, our focus shifts to lodging the formal FDA submission in the coming weeks. Gaining clearance will enable clinicians across the US to use EchoSolv HF as a powerful decision support software to improve the early and accurate detection of heart failure – a condition that remains significantly under-diagnosed and under-treated. We look forward to advancing this next phase and to working closely with healthcare partners as we prepare for a full commercial rollout."

- 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.

FORWARD-LOOKING STATEMENTS:

This announcement contains forward-looking statements regarding Echo IQ's expectations, intentions, and projections regarding future events, including statements about FDA 510(k) submission timing, potential FDA clearance of EchoSolv HF, commercialisation plans, market opportunities, and expected product performance. These forward-looking statements are based on current expectations and assumptions and are subject to risks, uncertainties, and other factors that could cause actual results to differ materially from those expressed or implied by such statements.

Key risks and uncertainties include, but are not limited to: the timing and outcome of the FDA 510(k) review process, which is uncertain and may result in delays, requests for additional information, or denial of clearance; regulatory requirements that may change or differ from expectations; the ability to successfully commercialise EchoSolv HF in the US market; market acceptance by healthcare professionals and institutions; competitive factors and the development of alternative technologies; reimbursement policies and healthcare spending trends; and the Company's ability to execute its commercialisation strategy. The Company's ability to achieve the market opportunities described in this announcement is subject to numerous factors beyond its control.

Actual results, performance, or achievements may differ materially from those expressed or implied in forward-looking statements. Echo IQ does not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by applicable law or ASX Listing Rules. Investors are cautioned not to place undue reliance on forward-looking statements.

[i] https://academic.oup.com/cardiovascres/article/118/17/3272/6527627?login=false#google_vignette
[ii] https://pmc.ncbi.nlm.nih.gov/articles/PMC9070116/
[iii] https://hfstats.org/stat-category/incidence-prevalence-and-lifetime-risk-estimates-of-hf-in-the-us/