ASX: EIQ RELEASE **24 December 2024**

ECHO IQ REQUESTS PRE-SUBMISSION MEETING WITH US FDA FOR HEART FAILURE CLINICAL DECISION SUPPORT SOLUTION CLEARANCE

- **Meeting request lodged with US FDA regarding clearance for EIQ's innovative heart failure clinical decision support solution ("EchoSolv HF")**
- **Pre-submission meeting expected to confirm our FDA regulatory strategy and US clinical validation study protocol**
- **Meeting expected to be undertaken during Q1 CY2025 with clearance for EchoSolv HF anticipated H2 CY2025**
- **Request follows two recently completed studies using EchoSolv HF to evaluate solution which demonstrated strong performance parameters:**
  - **EIQ's AI stand alone performance detected 86% of heart failure cases (vs 46% detection in standard clinical practice)**
  - **Combination of AI and clinical evaluation increased accuracy to 97% in high-risk individuals**
- **Company remains in well advanced negotiations with a number of prominent US-based healthcare organisations to undertake the proposed validation study**
- **Study expected to commence next quarter and mark the final clinical requirement, prior to a formal submission with the FDA for clearance**
- **Heart failure is a major addressable market for EIQ – it is the leading cause of re-hospitalisation in the US and accounts for 17% of all healthcare expenditure**
- **Heart failure has an estimated market size of US$60Bn annually**

Sydney: AI and Medical Technology company Echo IQ ("the Company" or "Echo IQ") (ASX:EIQ) is pleased to advise it has submitted a formal request to the US Food & Drug Administration ("FDA") for a pre-submission meeting to approve the design for a proposed validation trial which will test its heart failure screening tool ("EchoSolv HF") in detecting various forms of heart failure.

Heart failure is a widespread condition and the leading cause of re-hospitalisation in the US, accounting for 17% of all US healthcare expenditure[i]. The market for heart failure is estimated to be US$60Bn annually[ii] and presents a major opportunity for Echo IQ.

The request for the pre-submission meeting, which is expected to occur in the next 90 days, follows two recently completed clinical studies in collaboration with leading Australian research centres: St. Vincent's Institute of Medical Research and The University of Notre Dame, Fremantle (refer ASX announcement: 3 September 2024).

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When compared to an observed detection rate of 46% in clinical practice[iii] key findings from these studies showed that EIQ's AI technology without human review clearly and correctly identified 86% of patients with heart failure, in comparison to a matched group without heart failure. Further, a combination of the AI plus clinical evaluation increased accuracy to 97% in high-risk individuals.

During the pre-submission meeting, the Company will liaise with the FDA on its curated dossier on EchoSolv HF and confirm design of its validation study. The validation study is expected to mark the final clinical requirement, prior to a formal submission for clearance. The Company anticipates attaining clearance for EchoSolv HF during H2 CY2025.

The Company is in well advanced negotiations with a number of prominent US healthcare organisations to undertake the proposed validation study and will provide further updates over the coming weeks.

Management commentary:

Incoming CEO, Mr Dustin Haines said: *"This request marks an important step forward in the Company's clinical development pathway for its innovative heart failure solution, which is advancing well in close consultation with our FDA consultants and a number of high calibre potential research partners.*

We look forward to working alongside the regulatory body to gain further insight into the final requirements for FDA clearance for EchoSolv HF, which is anticipated to unlock a major market opportunity for Echo IQ and further highlight the Company's ability to deliver improved patient outcomes at scale."

Echo IQ Chair Andrew Grover added: *"To have made this formal request to the FDA highlights an important development for Echo IQ and follows a very strong year of operational progress. Following our recent clearance for EchoSolv AS, we have gained a solid understanding of the requirements for clearance for our heart failure solution and are confident that we can achieve FDA clearance for EchoSolv HF during the second half of CY2025. This process will be underpinned by collaborations with leading healthcare organisations in the form of a validation study, which we anticipate will further highlight the potential of our technology in the US market."*

- 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.

[i] https://academic.oup.com/cardiovascres/article/118/17/3272/6527627?login=false
[ii] https://pubmed.ncbi.nlm.nih.gov/35085762/
[iii] https://pmc.ncbi.nlm.nih.gov/articles/PMC9070116/