ASX: EIQ **17 September 2026**

EchoSolv HF FDA application update

- **Work underway with regulatory consultants and legal counsel to advance 510(k) clearance for EchoSolv HF with the US FDA**
- **Echo IQ believes there is a clear path forward to obtaining FDA clearance for EchoSolv HF and its progressing this as a priority – clearance could potentially be achieved over the coming quarters**
- **FDA's determination raised no concerns regarding the underlying technology or core functionality of EchoSolv HF, matters cited relate to aspects of statistical analysis supporting clinical validation**
- **Multiple pathways under assessment, including administrative appeal, FDA Ombudsman review, or a new 510(k) submission - EIQ confident clearance remains achievable under the 510(k) route**
- **Echo IQ remains committed to working alongside the FDA to address all matters cited in its determination**
- **No material impact to the strategic partner agreements following regulatory activity**

Sydney: AI and Medical Technology company Echo IQ ("the Company" or "Echo IQ") (ASX: EIQ) wishes to provide the following update to recent engagement with the US Food & Drug Administration ("FDA") for the Company's initial EchoSolv HF 510(k) application (refer ASX announcement: 8 September 2026).

Following receipt of the FDA's Not Substantially Equivalent ("NSE") determination and ongoing review of documentation, Echo IQ believes there is a clear path forward to obtaining FDA clearance for EchoSolv HF, which could be achieved over the coming quarters.

The Company has commenced work to address the issues cited by the FDA in issuing the NSE determination and will continue to assess potential pathways forward, alongside counsel and key regulatory advisors. As part of this process, Echo IQ remains committed to working closely with the FDA to address all matters cited in its determination.

Following a review of the FDA's feedback, the Company considers the matters cited to be limited to aspects of statistical analysis supporting the clinical validation. The Company's assessment has not identified concerns relating to the underlying technology or core functionality of the EchoSolv HF device, and Echo IQ remains confident that clearance remains achievable under the 510(k) route.

Echo IQ has identified multiple potential pathways to progress EchoSolv HF towards FDA clearance, including an administrative appeal of the NSE determination, seeking review through the FDA Ombudsman, or submitting a new 510(k) application.

A potential administrative appeal will allow the Company to challenge the FDA's scientific and regulatory conclusions regarding the NSE determination and to obtain the insights and context regarding the FDA's rationale. The timelines for this process are not strictly defined and, in certain circumstances, may be shorter than 90 days. If the Company were to file an administrative appeal, it may result in the NSE determination being overturned, the FDA reopening its review and potentially providing clearance of EchoSolv HF, or the FDA requesting that the Company resubmit a 510(k) for clearance, providing clarity on the matters Echo IQ must address to resolve the FDA's previously identified concerns and obtain clearance.

The Company is also giving consideration to whether it will approach the FDA Ombudsman, which can assist with supporting the Company in obtaining a procedural review of the NSE determination as well as assist the Company in supporting its clearance application for EchoSolv HF with the FDA review team.

Finally, 510(k) resubmission is another alternative which may provide a viable path for obtaining clearance. This process can be undertaken over the coming quarters.

The Company will keep investors and shareholders informed of its progress in obtaining clearance for EchoSolv HF. As stated previously, there has been no material impact to the strategic partner agreements the Company currently has in place including, but not limited to, those with Advara HeartCare, Mayo Clinic, and Pro Medicus Limited.

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

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ABOUT ECHO IQ

Echo IQ is an AI and medical technology company that develops proprietary software to improve clinical decision-making in cardiology. The Company's flagship product, EchoSolv AS, is FDA-cleared for use as a clinical decision support aid in the detection of severe aortic stenosis. Echo IQ is headquartered in Sydney, Australia, with US operations based in Greenville, Delaware.

Forward-Looking Statements:

This announcement contains forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933 and Section 21E of the U.S. Securities Exchange Act of 1934, and other applicable securities laws. Forward-looking statements include, among others, statements regarding: the Company's intended regulatory pathway for EchoSolv HF, including the potential filing of an administrative appeal, a new 510(k) submission, or other regulatory action, and the anticipated timing and outcome of any such steps; the terms and implementation of the convertible note arrangement and proposed commercial partnership with Pro Medicus Limited, including the further A$10 million investment tranche that is conditional on FDA clearance of EchoSolv HF; the completion, timing and intended use of proceeds of the institutional placement; the finalisation, scope and effect of the CMS Calendar Year 2027 OPPS proposed rule and the proposed interim Software as a Medical Service (SaMS) payment methodology, including EchoSolv's eligibility for reimbursement and any New Technology APC application; the conversion of the Company's commercial pipeline into executed contracts and deployments; expected echocardiogram processing volumes, revenue and market opportunity; and the Company's future strategy, growth and competitive position. Forward-looking statements can generally be identified by words such as "anticipate," "believe," "expect," "intend," "plan," "potential," "propose," "will," "would" and similar expressions. Forward-looking statements are not guarantees of future performance and are based on management's current expectations, estimates and assumptions as at the date of this announcement. They involve known and unknown risks, uncertainties, assumptions and other factors, many of which are beyond the Company's control, that may cause actual results, performance or achievements to differ materially from those expressed or implied. Such factors include, without limitation: the risk that a revised or new submission to the FDA will not be made or will not succeed; the risk that FDA clearance of EchoSolv HF may not be obtained within any particular timeframe, or at all; the risk that the Company's commercial plans for EchoSolv HF remain subject to obtaining required regulatory clearances; the risk that the convertible note arrangements with Pro Medicus are not completed on the proposed terms or at all, and that conditions to the additional subscription (including FDA clearance) are not satisfied; the risk that the CMS proposed rule is not finalised as proposed, or that EchoSolv does not qualify for the SaMS payment methodology or associated reimbursement; changes in applicable law, regulation, coding and reimbursement policy; the pace, cost and success of the Company's U.S. commercial expansion and customer adoption; competition; the Company's ability to protect and utilise its data assets; and general economic, market and industry conditions. Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as at the date of this announcement. Except as required by law or the ASX Listing Rules, the Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. Past performance is not an indicator or guarantee of future performance.