ASX: EIQ RELEASE **8 October 2024**

MAJOR MILESTONE ACHIEVED WITH FDA CLEARANCE SECURED FOR ECHOSOLV AS

Highlights:

- **510(k) clearance secured from FDA allows for EIQ's AI-enabled solution, EchoSolv AS to be marketed and sold in the USA**
- **Clearance marks a major milestone and will allow for rapid commercial scale up**
- **EIQ is in advanced discussions with a range of US healthcare providers around the potential uptake of EchoSolv AS – pipeline is well established with multiple groups**
- **Ongoing liaison with device manufacturers and pharmaceutical companies advancing to broaden commercialisation pipeline**
- **Work alongside US consultancy to obtain reimbursement codes for use of EchoSolv AS under insurance to scale up following FDA clearance**
- **Company is well funded to advance multiple, near-term commercialisation opportunities**
- **Advanced discussion with potential US based CEO with extensive healthcare, commercialisation and reimbursement experience.**

Sydney: AI and Medical Technology company Echo IQ Limited ("the Company") (ASX:EIQ) is pleased to advise that it has received 510(k) clearance from the US Food and Drug Administration (FDA) for EchoSolv AS, allowing for the solution to be marketed to and used by healthcare professionals in the USA as a decision support aid in the detection of severe Aortic Stenosis.

The clearance follows a formal submission in May 2024 (refer ASX announcement: 7 May 2024). Following detailed review, the FDA has determined that the Company demonstrated substantial equivalence to the predicate device cited in this submission, and has cleared it for marketing and use in the US.

Prior to securing FDA clearance, Echo IQ has been advancing discussions with a number of parties including large hospital groups, device manufacturers and pharmaceutical companies, on the commercial and clinical benefits of EchoSolv AS. As such, the Company is now exceptionally well placed to convert these negotiations into material agreements.

The Company will also scale up work alongside its US consultancy to obtain reimbursement codes for users of EchoSolv AS under insurance. This will create financial incentives for more widespread use of EchoSolv AS in US hospital settings on a fee-per-use basis.

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Following EIQ's recent capital raise (refer ASX announcement: 6 September 2024), the Company is well placed to deploy those funds towards commercialisation activities relating to EchoSolv AS, as well as furthering its product development of EchoSolv as a diagnosis tool for Heart Failure (refer ASX announcement: 3 September 2024).

With FDA approval for Echo IQ's EchoSolv AS granted, the Company now turns its attention to commercialising its products (both EchoSolv AS and its future range of products) in the US. The first critical step to delivering on this goal is the appointment of a suitably credentialed CEO based in the US who can lead the team. The Company has conducted interviews and is in the final stages of finalising arrangements for this appointment.

Management commentary:

Executive Chair, Mr Andrew Grover said: *"FDA clearance is major milestone for Echo IQ and provides the foundation to deliver a material value uplift for our shareholders. The Company now has the ability to commercialise its technology in the world's largest and most well-regulated market, for a condition which is widespread and chronically underdiagnosed."*

"EchoSolv AS shows significant improvements in the detection of severe Aortic Stenosis when compared to current clinical practice. Clearance follows an extensive R&D phase, which saw the solution rigorously tested in the US and Australia. The FDA's decision further validates the hard work undertaken by the Company and the results which were demonstrated from these initiatives."

"Following clearance, the Company is now aggressively focused on commercialisation. Prior to the FDA's decision, we have undertaken extensive discussions with a number of hospital groups in the US, as well as potential licencing opportunities with device manufacturers and pharmaceutical companies. We are now very well positioned to capitalise on these advanced negotiations and our well-established pipeline."

"FDA clearance also provides another catalyst to secure reimbursement codes, which have the potential to provide Echo IQ with a fee on a per use basis from large insurance groups. This is anticipated to underpin future revenues in the US market."

About Aortic Stenosis:

Aortic Stenosis is a form of heart valve disease, frequently caused by calcification of the aortic valve (commonly referred to as the gateway to the heart). Accurate and timely diagnosis of AS is challenging under current protocols, which means many sufferers are not receiving life extending and lifesaving treatments, such as valve replacement surgery. EchoSolv AS is designed to automatically highlight patients with significant risk of the disease in order to assist clinicians in decision-making for valve intervention and/or follow-up in a highly consistent, systematic and efficient manner.

About EchoSolv AS:

EchoSolv AS is a machine learning and AI-based decision support software specified for use as an adjunct to echocardiography for assessment of severe Aortic Stenosis. When used by an interpreting physician, EchoSolv AS provides information to facilitate rendering an accurate diagnosis of AS. EchoSolv AS includes both the algorithm-based Aortic Stenosis phenotype analysis and the application of recognised Aortic Stenosis clinical practice guidelines.

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

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