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Artrya submits FDA 510(k) Application for Salix® Coronary Plaque module

PERTH, Australia, 16 June 2025: Artrya Limited (ASX: AYA) (**Artrya** or the **Company**), a medical technology company commercialising its Salix® AI-powered cloud platform, for the near real-time, point-of-care assessment and management of coronary artery disease, announces that it has filed a 510(k) pre-market submission for the Salix® Coronary Plaque module with the U.S. Food and Drug Administration (**FDA**).

Key Points

- **510(k) application submitted to the FDA for the Salix® Coronary Plaque module which uses Artrya's proprietary artificial intelligence algorithms**
- **Salix® Coronary Plaque module enables near real-time, point-of-care detection of high-risk plaque - a key predictor of heart attack[1] often missed using current manual practices**
- **Salix® Coronary Plaque module integrates seamlessly with FDA-cleared Salix® Coronary Anatomy platform**
- **Upon FDA clearance, Salix® Coronary Plaque module will qualify for an existing U.S. Category 1 CPT code, with a reimbursement rate of US$950 for each automated plaque assessment**
- **FDA clearance for Salix® Coronary Plaque module is expected in the third quarter of 2025**

Mathew Regan, Chief Executive Officer of Artrya commented:

"We're pleased to have submitted our FDA application for the Salix® Coronary Plaque module, following the successful clearance of our Salix® Coronary Anatomy platform earlier this year. Building on that experience, we've developed strong clinical evidence for this submission showing our module's results closely match those of expert clinicians. We're also making strong progress finalising integration with our three U.S. hospital partners as we prepare for commercial launch in the US."

FDA 510(k) submission for Salix® Coronary Plaque module

Artrya has filed a 510(k) submission with the FDA for clearance of Salix® Coronary Plaque, a proprietary artificial intelligence-enabled module for detecting and quantifying coronary artery plaque. The Salix® Coronary Plaque module, once cleared, will enable a near real-time, point-of-care assessment of plaque and stenosis for patients who have undergone a coronary CT angiogram (**CCTA**).

The Salix® Coronary Plaque module, expected to receive FDA clearance in the third quarter of 2025, will integrate with the Salix® Coronary Anatomy platform, which received FDA clearance on 28 March 2025.

Commercial opportunity for Salix® Coronary Plaque module

Artrya already has strategic commercial agreements with three U.S. hospital partners, Northeast Georgia Health Ventures (a part of Northeast Georgia Health System), Healthliant Ventures (part Tanner Health System), and Cone Health. Together these systems operate 15 hospitals and multiple outpatient centres that perform a large number of CCTA scans each year. Artrya has begun rolling out the Salix® Coronary Anatomy in stages across these hospital system partners, with Salix® Coronary Plaque module set to launch shortly after FDA clearance.

Artrya is also collaborating with several major U.S. hospital centres to participate in the upcoming SAPPHIRE study. These centres will use the Salix® Coronary Plaque module, with the aim of becoming additional commercial launch sites following FDA clearance. The SAPPHIRE study will evaluate whether Artrya's novel Plaque Dispersion Score

[1] https://pubmed.ncbi.nlm.nih.gov/32174130/

(PDS) more accurately predicts patient risk than current methods, and whether it can help guide personalised therapy for those at highest risk. Participating centres will use the Salix® Coronary Anatomy platform to assess plaque on scans, contributing this data to a shared registry for the primary study which will also be available for a number of future sub-studies.

U.S. Reimbursement and Artrya Revenue Opportunity

Upon FDA clearance, Artrya's Salix® Coronary Plaque module will qualify for reimbursement under an existing CPT code for automated plaque analysis from CCTA scans. This code was upgraded to Category I in October 2024, with a reimbursement rate of US$950[2] per assessment. The Category I designation takes full effect on January 1, 2026, enabling Artrya to begin generating commercial revenue under the established code.

- Ends -

This ASX Announcement is authorised for release by the Board of Artrya Limited.

About Artrya

Artrya Limited (ASX: AYA) is an Australian medical technology company developing AI-powered solutions to improve the detection and management of coronary artery disease. Its proprietary software analyses coronary CT scans to identify key biomarkers of heart disease, supporting clinicians in diagnosing patients more accurately and efficiently. Artrya's mission is to advance cardiac care through innovative technology, with regulatory and commercial activities underway across key international markets.

For more information visit **www.artrya.com** or follow us on LinkedIn at **www.linkedin.com/company/artrya**

Forward Looking Statements

This Announcement may contain forward-looking statements, including estimates, projections and other forward-looking information (**Estimates** and **Projections**). Forward-looking statements can generally be identified by the use of forward-looking words such as "expect", "anticipate", "likely", "intend", "should", "could", "may", "predict", "plan", "propose", "will", "believe", "forecast", "estimate", "target", "outlook", "guidance" and other similar expressions within the meaning of securities laws of applicable jurisdictions and include, but are not limited to, indications of, or guidance or outlook on, future earnings or financial position or performance of Artrya. The Estimates and Projections are based on information available to Artrya as at the date of the Announcement, are based upon management's current expectations, estimates, projections, assumptions and beliefs in regard to future events in respect to Artrya's business and the industry in which it operates which may in time prove to be false, inaccurate or incorrect. The Estimates and Projections are provided as a general guide and should not be relied upon as an indication or guarantee of future performance. The bases for these statements are subject to risk and uncertainties that might be out of control of Artrya and may cause actual results to differ from the Announcement. No representation, warranty, or guarantee, whether express or implied, is made or given by Artrya in relation to any Estimates and Projections, the accuracy, reliability, or reasonableness of the assumptions on which the Estimates and Projections are based, or the process of formulating any Estimates and Projections, including that any Estimates and Projections contained in this Announcement will be achieved. Artrya takes no responsibility to make changes to these statements to reflect change of events or circumstances after the release.

[2] https://cardiovascularbusiness.com/topics/cardiac-imaging/cms-increases-medicare-payments-cardiac-ct-ccta

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