ARTRYA
Coronary Artery Disease.
We see you.

FDA clearance of Salix® Coronary Plaque module

Significantly expands U.S. commercial opportunity with ability to charge fees per scan assessed

Investor Webinar - 11.30am AEST (9.30am AWST) on 22 August 2025

PERTH, Australia, 21 August 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, is pleased to announce it has received 510(k) clearance from the U.S. Food and Drug Administration (the **FDA**) for Artrya's proprietary, Salix® Coronary Plaque module. This regulatory clearance is a major milestone in Artrya's U.S. market launch which commenced in July and will greatly expand the revenue opportunity with current and future customers.

Key Points

- **Major milestone as Artrya receives FDA 510(k) clearance for the Salix® Coronary Plaque module**
- **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 which is already commercial with Tanner Health**
- **Significantly expands U.S. commercial launch with ability to charge a fee per scan assessed with Salix® Coronary Plaque module - U.S. Category 1 CPT reimbursement rate US$950[2] for each assessment**

John Konstantopoulos, Co-Founder and CEO of Artrya, said:

"We are thrilled to have received FDA clearance of our Salix® Coronary Plaque module, which opens up a much greater revenue opportunity for us in the U.S., our largest market. The team have worked tremendously hard to prepare and support the submission which we lodged on the 16th of June, and we intend to build on this as we approach our next submission for the Salix® Coronary Flow module.

Our momentum is definitely building, with the core Salix® Coronary Anatomy platform now commercial in Tanner Health, and integration of Northeast Georgia Health System and Cone Health progressing well. Once live, we simply enable the Salix® Coronary Plaque module in their workstream, providing their clinicians access to our highly detailed assessment of coronary artery plaque in under ten minutes. We know these clinicians tremendously value the speed, ease and efficiency that our Salix® platform and plaque module offers, as they seek to rapidly diagnose patients and provide those in need with lifesaving treatment.

As we move forward, our ability to generate revenue from our U.S. customers for each CCTA scan they assess with our Salix® Plaque module, provides us the ability to scale rapidly. This is underpinned by the ability of our customers to receive an attractive Category 1 reimbursement of US$950[2] for each plaque assessment they perform."

FDA 510(k) clearance of Salix® Coronary Plaque module

Artrya has received FDA 510(k) clearance of the Salix® Coronary Plaque module, a proprietary artificial intelligence-enabled module for detecting and quantifying coronary artery plaque. The Salix® Coronary Plaque module enables a near real-time, point-of-care assessment of plaque and stenosis for patients who have undergone a coronary CT angiogram (**CCTA**). A CCTA scan is now the recommended front line diagnostic scan for assessing patients with known or suspected coronary artery disease.

The Salix® Coronary Plaque module is already embedded within the same user interface as the Salix® Coronary Anatomy platform and can immediately be enabled in the live version of the platform following this FDA clearance.

[1] Low-Attenuation Noncalcified Plaque on Coronary Computed Tomography Angiography Predicts Myocardial Infarction: Circulation. 2020;141(18):1452-1462. doi:10.1161/CIRCULATIONAHA.119.044720

[2] Cardiovascular Business – CMS significantly increases Medicare payments for cardiac CT

This makes the expanded Salix® technology offering available to clinicians, with assessments available to them in less than 10 minutes and without changing or using multiple systems, as required with competing technology.

Commercial opportunity for Salix® Coronary Plaque module

Coronary artery disease (CAD) remains the leading cause of death and the largest category of U.S. healthcare expenditure, with costs projected to exceed US$1 trillion by 2035[3]. Coronary artery plaque remains difficult to detect with current methods and in over 50%[4] of the population, the first sign of the disease is sudden death. More than 4.4 million[5] CCTA scans are performed each year in the U.S., growing at over 6% annually[6].

The U.S. government has also increased reimbursement rates paid for assessing CCTA scans, due to the high incidence and benefits for earlier intervention. Now that Artrya's Salix® Coronary Plaque module is cleared, it automatically qualifies for a Category I CPT code for automated plaque analysis of CCTA scans, with reimbursement of US$950 per assessment from January 1, 2026.

Artrya's go to market strategy for the U.S. is built around three strategic partnerships with mid-sized U.S. hospital systems. The first of these, Tanner Health, signed a commercial agreement for clinical use of the Salix® Coronary Anatomy platform in July 2025 and the integration of Northeast Georgia Health and Cone Health is progressing and will be completed in coming months. This is Artrya's most immediate commercial opportunity and will be the focus before adding additional customers.

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 and will gain awareness and understanding of the benefits that Salix® can provide. A key strategy moving forward will be to build on this awareness and clinical utility to seek to transition these centres to commercial customers.

Investor Webinar

The Company's Co-Founder and CEO John Konstantopoulos, will host an Investor Webinar at 11.30am AEST (9.30am AWST) on 22 August 2025, to discuss the FDA clearance and the business outlook. A recording of the webinar will be available on the Investor Centre section of the Company's website for 60 days after the call. Shareholders will also have an opportunity to participate in a Q&A session at the end of the briefing.

Date: 22 August 2025

Time: 9:30am AWST / 11:30pm AEST

To pre-register for this conference, please use the following link below:

https://artrya.zoom.us/webinar/register/WN_9ke5TnZATEGINQn6ZUq-VQ

- Ends -

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

[3] Cardiovascular Disease: A Costly Burden for America – Projections Through 2035. American Heart Association

[4] Comprehensive plaque assessment by coronary CT angiography. Nat Rev Cardiol 11, 390–402 (2014)

[5] Frost & Sullivan Analysis – Artrya Prospectus

[6] Diagnostic and Interventional Cardiology (DIAC) - Rising Demand for Cardiac CT Positions Market for Major Growth

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 regards 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.

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