ARTRYA®

ASX ANNOUNCEMENT
MARKET RELEASE
28 March 2025

Artrya secures milestone US FDA clearance for Salix® Coronary Anatomy

Highlights

- **The Food and Drug Administration (FDA) 510(k) has cleared Salix® Coronary Anatomy for commercial sale in the US**
- **Salix® is the first point of care approach in 50 years for assessing coronary artery disease, the world's leading cause of death.**
- **Salix® Coronary Anatomy will be formally launched across the hospital groups in the US where Salix® has been integrated within hospital workflows as part of a pre-FDA clearance validation phase.**

Artrya Limited (ASX:AYA), ('Artrya' or the 'Company'), a medical technology company focused on commercialising its patented AI platform that detects key coronary artery disease imaging markers, has secured US Food and Drug Administration (FDA) 510(k) clearance for Salix® Coronary Anatomy which allows Artrya to now commercialise in the US market.

Salix® Coronary Anatomy (SCA) delivers a non-invasive, point-of-care assessment within 10 minutes of a coronary computed tomography angiogram (CCTA) scan being taken, enabling physicians to quickly identify, analyse, and edit the extent and type of arterial plaque, the main cause of heart disease, along with stenosis and calcification, which provides a holistic view of patient risk.

During FY24, Artrya established Strategic Agreements with three US hospital groups: Northeast Georgia Health Ventures (NGHV), a part of Northeast Georgia Health System (NGHS), Healthliant Ventures, a part Tanner Health System, and Cone Health. Under these agreements, the hospital groups worked with Artrya to non-clinically validate and integrate Salix® Coronary Anatomy in their workflows, while the product progressed through the FDA 510(k) clearance process.

Now with FDA clearance, Artrya will work with these groups to commercially expand access to Salix® Coronary Anatomy across 15 hospitals, multiple outpatient centres, and dedicated heart and vascular centres across the US Southeast.

Artrya CEO Mathew Regan said: *"I am delighted to announce Salix® Coronary Anatomy has secured FDA clearance, paving the way for the official commercial launch into the US market.*

"For decades, heart disease has been treated reactively, waiting for symptoms to appear before taking action. With FDA clearance of Salix® Coronary Anatomy, hospitals and clinics can now move beyond traditional diagnostics to a truly proactive approach. Salix® is the first major advancement in 50 years that delivers a comprehensive point-of-care assessment within just 10 minutes. This not only improves the diagnosis and reporting workflow for coronary artery disease but also reduces unnecessary costs and can minimise patient readmissions.

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"With FDA clearance we can immediately begin the sales cycle, starting with our established hospital partnerships. This will allow us to accelerate commercialisation in the US market, where an estimated 4.4 million[1] CCTA scans are performed annually, growing at over 6% per year[2].

"Our strategic approach to securing FDA clearance for Salix® Coronary Anatomy has provided us with valuable insights into the FDA process, which we will leverage to expedite the clearance for our upcoming product submissions, starting with Salix® Coronary Plaque and then Salix® Coronary Flow. We anticipate FDA clearance for both products by the end of this calendar year, unlocking access to two distinct reimbursement codes for detailed plaque and blood flow analysis in the US healthcare market."

Investor Webinar

CEO Mathew Regan will host an investor webinar discussing the Company's milestone FDA clearance.

Shareholders will have an opportunity to participate in a Q&A session at the end of the webinar.

Date: 31 March 2025

Time: 9:00am AWST / 12:00pm AEDT

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

https://us02web.zoom.us/webinar/register/WN_GibVM3G2QC-u5_nB7xdiaA

This announcement was approved by the Board of Artrya Limited.

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About Artrya

Based in Perth, Australia, Artrya was founded in 2018 with operations starting in early 2019. The Company was listed on the Australian Securities Exchange (ASX: AYA) in 2021.

Artrya is an applied artificial intelligence healthcare company that works alongside clinicians to improve the diagnosis of coronary heart disease and develop a holistic overview of at-risk patients. The company has developed deep-learning algorithms pending regulatory submission for clearance and approval in the US that will serve to predict and prevent acute coronary events.

For more information, see www.artrya.com

Note: Salix® Coronary Anatomy is cleared by the Food and Drug Administration (FDA) as Salix Central K243038

[1] Frost & Sullivan Analysis – Artrya Prospectus – https://wcsecure.weblink.com.au/pdf/AYA/02456983.pdf

[2] https://www.dicardiology.com/article/rising-demand-cardiac-ct-positions-market-major-growth