ARTRYA®
Coronary Artery Disease.
We see you.

Salix® Coronary Flow Update – Successful Q-Submission meeting with FDA

Clear guidance provided by FDA for Salix® Coronary Flow 510(k) submission

PERTH, Australia, 10 October 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 provide an update on a successful Q-Submission meeting held with U.S. Food and Drug Administration (**FDA**) as it pursues regulatory clearance for the Salix® Coronary Flow module.

Highlights

- **Q-Submission meeting with FDA provided clear guidance for Salix® Coronary Flow submission.**
- **FDA confirmed 510(k) pre-market application as the appropriate regulatory pathway.**
- **Study design and 510(k) application to be updated to incorporate FDA feedback.**

Artrya has successfully completed a Q-Submission (**Q-Sub**) meeting with the FDA, a key step in advancing the regulatory pathway for the Salix® Coronary Flow (**SCF**) module. The Q-Sub is a formal written request from the Company for feedback from the FDA to help guide the planned 510(k) application.

During the meeting, the FDA provided constructive guidance on the pathway to 510(k) regulatory clearance. Incorporating this feedback, Artrya will refine the Salix® Coronary Flow 510(k) application, marking an important step toward a successful submission.

John Konstantopoulos, Co-Founder and CEO of Artrya commented:
"Following the successful approval of Salix® Coronary Plaque in August, we have been progressing the FDA submission process for our Salix® Coronary Flow module. As part of this process, a formal Q-Sub meeting with the FDA was conducted to obtain feedback on our regulatory strategy, intended use, and clinical validation requirements. The meeting provided valuable guidance and confirmed a clear pathway to 510(k) clearance. We plan to adopt a similar approach to that used for Salix® Coronary Plaque, focusing on a robust clinical study and high-quality submission to support an expedited approval process."

The final 510(k) pre-market application for the SCF module is expected to be submitted to the FDA by end of the calendar year.

- 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

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