

ASX ANNOUNCEMENT

MARKET RELEASE

20 August 2024

Artrya on track for FDA application submission following second Q-Submission meeting

Highlights

- **Feedback and guidance were received during a second Q-Submission meeting held on the evening of 19 August 2024**
- **Artrya received feedback its application for regulatory approval for Salix product with the US FDA is on track**
- **Artrya plans to submit the 510(k) application to the FDA in the coming weeks.**

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 received feedback its application for regulatory approval for the Salix product with the US Food and Drug Administration (FDA) is on track following a Q-Submission meeting.

As stated in Artrya's 4Q FY24 report to the ASX, the Company had requested a second Q-Submission (Q-Sub) meeting as a key step in the process to finalise its US FDA application for Salix. The meeting was held on the evening of 19 August 2024.

A Q-sub is a formal written request from a company for feedback from the FDA to help guide application preparation. Artrya had requested this second meeting to validate and confirm the approach taken since the first Q-Sub meeting in June 2023.

Artrya CEO Mathew Regan said: *"I am pleased to report the outcome of our second Q-sub meeting with the FDA was positive. The FDA provided valuable feedback and guidance on our upcoming application, confirming our approach is on track. This has validated the cautious approach we have taken to ensure we meet all requirements for the 510(k) application. We now have a clear path to submission, and I look forward to lodging our 510(k) application once the formal Q-Sub process is completed."*

This announcement was approved by the Board.

For further information please contact:

Investor Enquiries:

Danny Younis

[+61 420 293 042](tel:+61420293042)

danny.younis@automicgroup.com.au

Media Relations:

Tristan Everett

+61 403 789 096

tristan.everett@automicgroup.com.au

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

For personal use only