

ASX ANNOUNCEMENT

MARKET RELEASE

30 September 2024

Artrya submits 510(k) application to the US FDA

Highlights

- Artrya submits 510(k) application to the US Food and Drug Administration (FDA) for regulatory approval of its Salix® Coronary Anatomy product
- This follows feedback from the FDA in two Q-Submission (Q-sub) meetings

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 submitted its application for regulatory approval for the Salix® Coronary Anatomy product with the US Food and Drug Administration (FDA).

This follows feedback from the FDA in two Q-Submission (Q-sub) meetings in June 2023 and August 2024. Q-sub meetings are a key part of the application process which consist of formal written requests from a company and resulting meetings for feedback from the FDA to help guide the preparation of applications. These meetings validated and confirmed the approach that Artrya has taken to ensure it meets requirements for a compliant 510(k) application. This is the first 510(k) application in a series currently anticipated in Artrya's product roadmap, allowing Artrya to access the US market post approval and providing the foundation for further applications such as more detailed plaque quantification and Fractional Flow Reserve (FFR), amongst others.

Artrya CEO Mathew Regan said: "I am pleased to report that Artrya has submitted its FDA application for regulatory approval of our Salix® Coronary Anatomy product, after completing key stages of preparation. We look forward to hearing from the FDA in due course. Over the last 10 months we have also worked with US hospital groups and healthcare systems in strategic agreements to do final testing and validation on the Artrya system, which will allow us to reduce the sales cycle post FDA approval."

This announcement was approved by the Board.

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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