

ASX ANNOUNCEMENT MARKET RELEASE

3 May 2023

Artrya lodges key submission in FDA process

Key Points:

- Q-Submission (Q-Sub) goes to FDA
 - Q-Sub meeting expected within three months
 - 510(k) application on track as previously advised
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Perth, Western Australia, (3 May 2023) – Australian medical technology company, Artrya Limited (ASX: AYA) (Artrya or the Company) today announces important progress in the pursuit of US Food and Drug Administration (FDA) regulatory approval for the Salix Coronary Anatomy (SCA) product.

As foreshadowed in the recent quarterly update, the company can confirm that a Q-Submission (Q-Sub) has now been lodged with the FDA, a key enabling step in the US regulatory process. Artrya expects a Q-Sub meeting with the FDA within 9 to 12 weeks.

The Q-Sub meeting is an important part of the FDA process at which Artrya will present its approach to software development and clinical reader study design to get FDA agreement on how the product is being developed.

Artrya Chief Executive Officer, Mathew Regan said the Q-sub meeting will allow Artrya to obtain invaluable feedback on our regulatory strategy, product definition, indications for use, and product testing and clinical validation requirements.

"This feedback can save critical time and money during the FDA regulatory process," Mr. Regan said.

"Since Artrya redefined its' FDA regulatory strategy in quarter one, the team has worked hard to get us to this point," he said.

It is expected that the final 510(k) application will be able to be submitted to the FDA by the end of October 2023. This remains in line with previous advice to the market.

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About Artrya

Based in Perth, Western Australia, Artrya was founded in 2018 and commenced operations in early 2019. Artrya Ltd is listed on the Australian Securities Exchange (ASX: AYA). Artrya is an applied artificial intelligence healthcare company that works alongside clinicians to improve the diagnosis of coronary artery disease and develop a holistic overview of a patient at risk. Artrya has developed deep learning algorithms that will streamline how medical care for heart disease is delivered. Artrya USA Inc. is a wholly owned subsidiary of Artrya Limited.

For more information: www.artrya.com