ARTRYA™

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ASX ANNOUNCEMENT
MARKET RELEASE

9 June 2023

Artrya conducts successful Q-Submission meeting with FDA

Key Points:

- Successful Q-Submission (Q-Sub) meeting with FDA provided clear direction for 510k submission.
- The FDA has agreed that a 510k pre-market application is the appropriate pathway.
- The FDA has agreed to considering our Point-of-Care approach, upon satisfying required agency recommendations.

Perth, Western Australia, (9 June 2023) – Australian medical device, digital health technology company, Artrya Limited (ASX: AYA) (Artrya or the Company) today announces it has completed a successful meeting with US Food and Drug Administration (FDA) as it pursues regulatory clearance for the Salix Software System product that aids radiologist and cardiologists in the analysis of 2D/3D coronary images acquired from Coronary Computed Tomography Angiographic (CCTA) scans.

As foreshadowed in May, the Q-Submission meeting has been held with FDA in the USA. This is a key step in increasing our success in the US regulatory process.

During the Q-Sub meeting, Artrya and the FDA agreed on a pathway to 510k regulatory clearance for the Salix product. Artrya discussed their multi-reader, multi-site study with the FDA and received feedback on the study design in preparation for their 510k submission.

The Artrya 510k application will now be updated to include feedback and guidance from the FDA and is a critical step for a successful 510k submission.

Artrya Chief Executive Officer, Mathew Regan said the Q-sub meeting enabled Artrya to obtain invaluable feedback on our regulatory strategy, product definition, intended use, product performance & testing, and clinical validation requirements.

"This is a significant moment for Artrya. We have received excellent feedback from the FDA and are confident of a pathway to 510k clearance assuming we meet the criteria agreed upon with the FDA," Mr. Regan said.

Artrya Chief Regulatory Affairs & Quality Officer, Dr. Richard M. Stewart, said he was very pleased with the outcome of the meeting.

"This was a very productive meeting. We can now move forward confidently with a clear picture of what the FDA expects from us," he said.

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"There is still hard work to be done to complete the process, but we are excited to be progressing on the path to US regulatory approval," he said.

Artrya's Chief Medical Officer said the meeting provided key clinical guidance towards a successful submission. "Going forward, Artrya will perform a clinical validation study with expert clinicians from several key institutes and hospital groups within the US. This study will validate that our software is safe and effective and also put the software in the hands of clinicians in the US for testing, prior to our formal FDA submission." Dr Jacob Agris, MD said.

It is expected that the final 510k pre-market application will be able to be submitted to the FDA in due course and 510k clearance is subject to FDA final review and approval. This remains in line with previous advice to the market.

This announcement was approved and authorised for release by the Board of Artrya Limited.

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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