

ASX ANNOUNCEMENT MARKET RELEASE

27 October 2022

ARTRYA SUCCESSFUL IN GAINING EUROPEAN REGULATORY APPROVAL

Perth, Western Australia., (27 October 2022): Australian medical technology company, Artrya Limited (ASX: AYA, Artrya or the Company) today received advice that it has received regulatory approval for its Salix Coronary Anatomy (SCA) product in Europe.

Artrya's European Notified Body (BSI) has notified the company that the assessment for European CE Marking has been completed and they will recommend certification of the Salix V2.0 Software for marketing into Europe.

The BSI assessment scope includes European EC certification in accordance with the European Medical Device Regulations 2017/745.

Once the EC certificate has been issued by BSI, Artrya is able to market the Salix software in 28 European Economic Area member countries.

The Conformance Europeenne Marking certifies that a product has met EU health, safety, and environmental requirements, which ensure consumer safety.

Artrya Managing Director and CEO John Barrington AM said this was an important moment for the company.

"We are pleased to receive this significant regulatory approval for what is a substantial future market opportunity," he said.

The Company continues to progress with the UKCA regulatory process, with Artrya passing two further assessment stages last quarter.

Artrya Salix is already listed on the Australian Register of Therapeutic Goods (ID 347719). Commercial release of SCA in Australia is planned for release during FY23.

On the basis of the Australian regulatory approval (ARTG 347719), the Salix Coronary Anatomy product received NZ Medsafe registration in July 2022. This will allow the company to commercialise the product in the New Zealand market.

This announcement was approved by the Artrya Managing Director and CEO.

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About Artrya

Based in Perth, 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 heart disease and develop a holistic overview of a patient at risk. The company has developed deep learning algorithms that will allow for the prediction and prevention of acute coronary events.

For more information, see www.artrya.com