



## **Amarin Announces Vascepa® (Icosapent Ethyl) Approved to Reduce Cardiovascular Risk in the Kingdom of Saudi Arabia (KSA)**

June 21, 2023

*-- VASCEPA® Approved in KSA To Reduce the Risk of Cardiovascular (CV) Events as an Adjunct to Statin Therapy in Adult Patients with Elevated Triglyceride (TG) Levels ( $\geq 150$  mg/dL) and Other High-Risk Characteristics as Studied in REDUCE-IT--*

*-- VASCEPA Becomes First and Only Approved Medication in KSA for Reducing CV Risk Beyond Cholesterol Lowering Therapy in High-Risk Statin Treated Patients with Elevated and High Triglyceride Levels --*

DUBLIN, Ireland and BRIDGEWATER, N.J., June 21, 2023 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) and its commercialization partner Biologix FZco, a company based in the United Arab Emirates and a pioneer in the distribution of pharmaceutical and biological products in the Middle East and North Africa, today announced that the Kingdom of Saudi Arabia's (KSA) Saudi Food and Drug Authority (SFDA) has approved a new indication and label expansion for VASCEPA® (icosapent ethyl) capsules. VASCEPA is now the first and only drug approved by SFDA as an adjunct to statin therapy in adult patients with elevated triglycerides (TG) levels ( $\geq 150$  mg/dL) who are at high-risk of cardiovascular (CV) events due to established cardiovascular disease or diabetes mellitus and at least one other risk factor for cardiovascular disease.

There is an urgent need to address cardiovascular disease (CVD) in KSA.<sup>i</sup> Over 30 percent of adults (18 years) in KSA are at risk of a CVD event.<sup>1</sup>

"We are excited that patients in KSA will now have the opportunity to benefit from the proven cardiovascular risk reduction with VASCEPA following the approval by the SFDA," said Steven Ketchum, PhD., President, Research & Development and Chief Scientific Officer, Amarin. "Today's approval also marks an important step in our strategy to expand the global footprint where VASCEPA/VASKEPA is indicated for cardiovascular risk reduction, built from the results seen in the REDUCE-IT outcomes trial. By executing against this strategy, we can bring the cardiovascular risk reduction benefit of VASCEPA/VASKEPA to millions more patients around the world."

Both the Saudi National Diabetes Center (SNDC) and The National Heart Center (NHC) in their published guidelines for diabetes and dyslipidemia, under the Saudi Health Council (SHC), mention icosapent ethyl (IPE) for CV risk reduction as an adjunct to statin therapy in patients with elevated and high TG levels.<sup>ii,iii</sup> The inclusion of IPE in the Saudi Diabetes Clinical Practice Guidelines (SDCPG)-2021 was done based on the results of the REDUCE-IT trial and publications, and prior to product registration in KSA.

Under a previously announced agreement between Amarin and Biologix, Biologix is responsible for registering VASCEPA in the licensed territory, as well as providing all marketing, sales, and distribution services for the product. Amarin is responsible for providing regulatory assistance, supply and maintaining intellectual property in the region.

### **About Amarin**

Amarin is an innovative pharmaceutical company leading a new paradigm in cardiovascular disease management. We are committed to increasing the scientific understanding of the cardiovascular risk that persists beyond traditional therapies and advancing the treatment of that risk for patients worldwide. Amarin has offices in Bridgewater, New Jersey in the United States, Dublin in Ireland, Zug in Switzerland, and other countries in Europe as well as commercial partners and suppliers around the world.

### **About Biologix**

Biologix FZ co, a privately owned pharmaceutical company organized and existing under the laws of the United Arab Emirates (UAE), was incorporated in the Dubai Airport Free Zone in September 2002 as a regional distributor and promoter of pharmaceutical specialties in the Middle East & North Africa (MENA) countries. Biologix provides end to end services from the pre-registration phase including named patient supply, medical and disease awareness activities, to registration, promotion, cold chain distribution, tender management, market access programs, pharmacovigilance and product safety, as well as the administration of risk management plans, on behalf of its partners. Biologix focuses on the following therapeutics areas: hematology-oncology, cardiology, immunology and rare diseases.

[www.biologixpharma.com](http://www.biologixpharma.com)

### **Forward-Looking Statements**

This press release contains forward-looking statements which are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including beliefs about Amarin's regulatory approval in the Kingdom of Saudi Arabia (KSA); the patient population and market potential for VASCEPA in KSA; and the overall potential and future success of VASCEPA/VAZKEPA generally. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. A further list and description of these risks, uncertainties and other risks associated with an investment in Amarin can be found in Amarin's filings with the U.S. Securities and Exchange Commission, including Amarin's annual report on Form 10-K for the full year ended 2022. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date they are made. Amarin undertakes no obligation to update or revise the information contained in its forward-looking statements, whether as a result of new information, future events or circumstances or otherwise. Amarin's forward-looking statements do not reflect the potential impact of significant transactions the company may enter into, such as mergers, acquisitions, dispositions, joint ventures or any material agreements that Amarin may enter into, amend or terminate.

### **Availability of Other Information About Amarin**

Amarin communicates with its investors and the public using the company website ([www.amarincorp.com](http://www.amarincorp.com)) and the investor relations website ([investor.amarincorp.com](http://investor.amarincorp.com)), including but not limited to investor presentations and FAQs, Securities and Exchange Commission filings, press releases, public conference calls and webcasts. The information that Amarin posts on these channels and websites could be deemed to be material information. As a result, Amarin encourages investors, the media and others interested in Amarin to review the information that is posted on these channels, including the investor relations website, on a regular basis. This list of channels may be updated from time to time on Amarin's investor relations website and may include social media channels. The contents of Amarin's website or these channels, or any other website that may be accessed from its website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

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<sup>i</sup> Saudi Health Council – National Heart Center. Cardiovascular Disease: A Public Health Priority. March 2022. [chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://shc.gov.sa/Arabic/NHC/Activities/Documents/Cardiovascular%20disease%20in%20KSA%20-%20a%20public%20health%20priority.pdf](https://shc.gov.sa/Arabic/NHC/Activities/Documents/Cardiovascular%20disease%20in%20KSA%20-%20a%20public%20health%20priority.pdf) (Accessed May 2, 2023).

<sup>ii</sup> Saudi Diabetes Clinical Practice Guidelines (SDCPG). 2021. Available at: <https://www.moh.gov.sa/Ministry/MediaCenter/Publications/Documents/Saudi-Diabetes-Clinical-Practice-Guidelines.pdf>. Accessed: May 2, 2023.

<sup>iii</sup> AlRahimi J, AlSaif S, Alasnag M, et al. *Saudi Guidelines for Dyslipidemia Management*. Saudi Health Council; 2022.