



## Latest Research Evaluating VASCEPA®/VAZKEPA (icosapent ethyl) and Subgroups from the REDUCE-IT® Landmark Outcomes Trial to be Presented at the European Society of Cardiology (ESC) Congress

August 15, 2022

DUBLIN, Ireland and BRIDGEWATER, N.J., Aug. 15, 2022 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) today announced new supported and/or funded research on the effects of VASCEPA®/VAZKEPA (icosapent ethyl) in specific patient subgroups at increased risk of a cardiovascular (CV) event from the landmark REDUCE-IT® cardiovascular outcomes trial have been accepted for presentation at the European Society of Cardiology (ESC) Congress, both online and onsite in Barcelona, August 26-29, 2022.

The accepted abstracts include a Late-Breaking Science presentation on reduction of ST-segment Elevation MI with VASCEPA from the REDUCE-IT trial. These and other new findings will be presented by a variety of international academic collaborators based on research or analyses supported by Amarin.

Featured Amarin-supported abstracts to be presented at ESC Congress 2022 include:

### **Late-Breaking Science Presentation**

- **Session:** Latest science in primary and secondary prevention and environmental health  
**“Significant Reduction in ST-Elevation MI with Icosapent Ethyl in REDUCE-IT”**  
Deepak L. Bhatt, Robert P. Giugliano, Ph. Gabriel Steg, Michael Miller, et al.

– Available August 26 at 2:18 p.m. CEST (8:18 a.m. EST) in room: Dali

### **Abstract Sessions Presentation**

- **Session:** *Optimal risk factor therapy in high risk patients*  
**“Icosapent Ethyl Diminishes CVD Risk in Smokers: REDUCE-IT Smoking”**  
Michael Miller, Deepak L. Bhatt, Ph. Gabriel Steg, Eliot A. Brinton, et al.

– Available August 28 at 11:50 a.m. CEST (5:50 a.m. EST) in room: Science Box 3

“We are pleased to support these Late Breaking Science and Oral Presentations at the upcoming ESC Congress being held later this month,” said Nabil Abadir, MB. CH.B., SVP, Chief Medical Officer and Head of Global Medical Affairs, Amarin. “These data continue to underscore the clinical and therapeutic utility and value of VASCEPA/VAZKEPA and continue to validate the clinical outcomes shown in the overall REDUCE-IT trial. As we know, REDUCE-IT demonstrated the clear risk reduction benefits of icosapent ethyl in reducing cardiovascular events among patients most at risk for cardiovascular disease including those with previous cardiovascular events, such as myocardial infarction (MI) or stroke. We are proud of the continued work that is being done to further demonstrate the proven efficacy of VASCEPA in cardiovascular risk reduction while providing support to investigators to explore other ways in which VASCEPA can potentially help patients and impact public health.”

### **About Amarin**

Amarin is an innovative pharmaceutical company leading a new paradigm in cardiovascular disease management. From our scientific research foundation to our focus on clinical trials, and now our commercial expansion, we are evolving and growing rapidly. Amarin has offices in Bridgewater, New Jersey in the United States, Dublin in Ireland, and Zug in Switzerland as well as commercial partners and suppliers around the world. We are committed to rethinking cardiovascular risk through the advancement of scientific understanding of the impact on society of significant residual risk that exists beyond traditional therapies, such as statins for cholesterol management.

### **About Cardiovascular Risk**

Cardiovascular disease is the number one cause of death in the world. In the United States alone, cardiovascular disease results in 859,000 deaths per year.<sup>1</sup> And the number of deaths in the United States attributed to cardiovascular disease continues to rise. In addition, in the United States there are 605,000 new and 200,000 recurrent heart attacks per year (approximately 1 every 40 seconds). Stroke rates are 795,000 per year (approximately 1 every 40 seconds), accounting for 1 of every 19 U.S. deaths. In aggregate, in the United States alone, there are more than 2.4 million major adverse cardiovascular events per year from cardiovascular disease or, on average, 1 every 13 seconds.

Controlling bad cholesterol, also known as LDL-C, is one way to reduce a patient’s risk for cardiovascular events, such as heart attack, stroke or death. However, even with the achievement of target LDL-C levels, millions of patients still have significant and

persistent risk of cardiovascular events, especially those patients with elevated triglycerides. Statin therapy has been shown to control LDL-C, thereby reducing the risk of cardiovascular events by 25-35%.<sup>2</sup> Significant cardiovascular risk remains after statin therapy. People with elevated triglycerides have 35% more cardiovascular events compared to people with normal (in range) triglycerides taking statins.<sup>3,4,5</sup>

#### **About REDUCE-IT®**

REDUCE-IT was a global cardiovascular outcomes study designed to evaluate the effect of VASCEPA in adult patients with LDL-C controlled to between 41-100 mg/dL (median baseline 75 mg/dL) by statin therapy and various cardiovascular risk factors including persistent elevated triglycerides between 135-499 mg/dL (median baseline 216 mg/dL) and either established cardiovascular disease (secondary prevention cohort) or diabetes mellitus and at least one other cardiovascular risk factor (primary prevention cohort).

REDUCE-IT, conducted over seven years and completed in 2018, followed 8,179 patients at over 400 clinical sites in 11 countries with the largest number of sites located within the United States. REDUCE-IT was conducted based on a special protocol assessment agreement with FDA. The design of the REDUCE-IT study was published in March 2017 in *Clinical Cardiology*.<sup>6</sup> The primary results of REDUCE-IT were published in *The New England Journal of Medicine* in November 2018.<sup>7</sup> The total events results of REDUCE-IT were published in the *Journal of the American College of Cardiology* in March 2019.<sup>8</sup> These and other publications can be found in the R&D section on the company's website at [www.amarincorp.com](http://www.amarincorp.com).

#### **About VASCEPA®/VAZKEPA® (icosapent ethyl) Capsules**

VASCEPA capsules are the first prescription treatment approved by the U.S. Food and Drug Administration (FDA) comprised solely of the active ingredient, icosapent ethyl, a unique form of eicosapentaenoic acid. VASCEPA was launched in the United States in January 2020 as the first and only drug approved by the U.S. FDA for treatment of the studied high-risk patients with persistent cardiovascular risk after statin therapy. VASCEPA was initially launched in the United States in 2013 based on the drug's initial FDA approved indication for use as an adjunct therapy to diet to reduce triglyceride levels in adult patients with severe ( $\geq 500$  mg/dL) hypertriglyceridemia. Since launch, VASCEPA has been prescribed over 18 million times. VASCEPA is covered by most major medical insurance plans. In addition to the United States, icosapent ethyl is approved and sold in Canada, Lebanon, Germany and the United Arab Emirates. In Europe, in March 2021 marketing authorization was granted to icosapent ethyl in the European Union for the reduction of risk of cardiovascular events in patients at high cardiovascular risk, under the brand name VAZKEPA. In April 2021 marketing authorization for VAZKEPA (icosapent ethyl) was granted in Great Britain. The Great Britain Marketing Authorization for VAZKEPA applies to England, Scotland and Wales.

#### **United States**

##### **Indications and Limitation of Use**

VASCEPA is indicated:

- As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels ( $\geq 150$  mg/dL) and
  - established cardiovascular disease or
  - diabetes mellitus and two or more additional risk factors for cardiovascular disease.
- As an adjunct to diet to reduce TG levels in adult patients with severe ( $\geq 500$  mg/dL) hypertriglyceridemia.

The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

#### **Important Safety Information**

- VASCEPA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to VASCEPA or any of its components.
- VASCEPA was associated with an increased risk (3% vs 2%) of atrial fibrillation or atrial flutter requiring hospitalization in a double-blind, placebo-controlled trial. The incidence of atrial fibrillation was greater in patients with a previous history of atrial fibrillation or atrial flutter.
- It is not known whether patients with allergies to fish and/or shellfish are at an increased risk of an allergic reaction to VASCEPA. Patients with such allergies should discontinue VASCEPA if any reactions occur.
- VASCEPA was associated with an increased risk (12% vs 10%) of bleeding in a double-blind, placebo-controlled trial. The incidence of bleeding was greater in patients receiving concomitant antithrombotic medications, such as aspirin, clopidogrel or warfarin.
- Common adverse reactions in the cardiovascular outcomes trial (incidence  $\geq 3\%$  and  $\geq 1\%$  more frequent than placebo): musculoskeletal pain (4% vs 3%), peripheral edema (7% vs 5%), constipation (5% vs 4%), gout (4% vs 3%), and atrial fibrillation (5% vs 4%).
- Common adverse reactions in the hypertriglyceridemia trials (incidence  $>1\%$  more frequent than placebo): arthralgia (2% vs 1%) and oropharyngeal pain (1% vs 0.3%).
- Adverse events may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.
- Patients receiving VASCEPA and concomitant anticoagulants and/or anti-platelet agents should be monitored for bleeding.

FULL U.S. FDA-APPROVED VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT [WWW.VASCEPA.COM](http://WWW.VASCEPA.COM).

## **Europe**

For further information about the Summary of Product Characteristics (SmPC) for VAZKEPA® in Europe, please [click here](#). Globally, prescribing information varies; refer to the individual country product label for complete information.

## **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 the potential for VASCEPA (marketed as VAZKEPA in Europe); beliefs about icosapent ethyl (IPE)'s role concerning patients suffering from cardiovascular disease (CVD) and impacts on the risk of heart attack, stroke or other fatal or non-fatal cardiovascular events for patients who suffered a prior heart attack, as well as general beliefs about the safety and effectiveness of VASCEPA. 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 2021. 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 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, 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.

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

Investors and others should note that Amarin communicates with its investors and the public using the company website ([www.amarincorp.com](http://www.amarincorp.com)), the investor relations website ([investor.amarincorp.com](http://investor.amarincorp.com)), including but not limited to investor presentations and investor 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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