



Research Highlighting the Clinical Impact of VASCEPA®/VAZKEPA (icosapent ethyl) in Patients with Diabetes and High Cardiovascular Risk and the Anti-Lp(a) Oxidation Mechanistic Effect of Eicosapentaenoic Acid (EPA) to be Presented at the 60th Annual European Association for the Study of Diabetes (EASD) Meeting

September 9, 2024

DUBLIN, Ireland and BRIDGEWATER, N.J., Sept. 09, 2024 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) today announced that new supported and/or funded research on the clinical impact of VASCEPA®/VAZKEPA (icosapent ethyl) in patients with diabetes and high cardiovascular risk and the anti-Lp(a) oxidation mechanistic effects of eicosapentaenoic acid (EPA) will be presented at the 60th Annual European Association for the Study of Diabetes (EASD) Meeting September 9 – 13, 2024 in Madrid, Spain.

The two accepted abstracts, which will be presented by international academic collaborators who have partnered with Amarin, include:

- A post-hoc analysis from the REDUCE-IT trial examining the effect of VASCEPA/VAZKEPA (icosapent ethyl) on a subgroup of patients with established cardiovascular disease and diabetes mellitus (DM) at baseline with a history of coronary artery bypass grafting (CABG) surgery; and
- An in-vitro analysis of EPA and its effects on lipoprotein(a) oxidation under normal and high glucose conditions that reproduce hyperglycemia in vivo.

“As has been well-proven, patients with established cardiovascular disease and diabetes mellitus are at increased risk of future cardiovascular events, especially in patients with elevated levels of Lp(a), making it the main cause of mortality among these patients.” said Nabil Abadir, Chief Medical Officer. “It is therefore imperative that we continue to focus on and invest in science to better understand different therapies that can have a potential impact on helping these patients reduce their risk of yet another cardiovascular event. We remain committed to partnering with cardiovascular researchers to further our understanding of icosapent ethyl and EPA and their potential impact on reducing cardiovascular risk in this vulnerable patient sub-population.”

Presentation Information:

Title: [Eicosapentaenoic acid inhibits lipoprotein\(a\) oxidation under normal and high glucose conditions in vitro](#)

Session: SO 097 Pathogenesis of diabetes complications

Date & Time: Tuesday, September 10, 2024; 12:30 PM CEST

Presenter: P. Mason

Title: [Reduction in ischaemic events with icosapent ethyl in patients with diabetes and prior CABG: REDUCE-IT diabetes-prior CABG](#)

Session: OP 21 Cardiovascular risk in diabetes: in search of the holy grail

Date & Time: Wednesday, September 11, 2024; 3:30 PM CEST

Presenter: S. Verma

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 at-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 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). Conducted over seven years and completed in 2018, REDUCE-IT followed 8,179 patients at over 400 clinical sites in 11 countries with the largest number of sites located within the United States, and was conducted based on a special protocol assessment agreement with the U.S. Food and Drug Administration (FDA). The design of the REDUCE-IT study was published in March 2017 in *Clinical Cardiology*.^{1 2} These and other publications can be found in the Science section on the company's website at www.amarincorp.com.

About VASCEPA® (icosapent ethyl) Capsules

VASCEPA (icosapent ethyl) capsules are the first prescription treatment approved by the U.S. Food and Drug Administration (FDA) comprised solely of the active ingredient, icosapent ethyl (IPE), a unique form of eicosapentaenoic acid. VASCEPA was launched in the United States in January 2020 as the first drug approved by the U.S. FDA for treatment of the studied high-risk patients with persistent cardiovascular risk despite being on 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 (≥ 500 mg/dL) hypertriglyceridemia. Since launch, VASCEPA has been prescribed more than ten million times. VASCEPA is covered by most major medical insurance plans. In addition to the United States, VASCEPA is approved and sold in Canada, Germany, Lebanon 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.

Indications and Limitation of Use (in the United States)

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 (≥ 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 (≥ 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 $\geq 1\%$ 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](http://www.vascepa.com) CAN BE FOUND AT [WWW.VASCEPA.COM](http://www.vascepa.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 the potential for VASCEPA (marketed as VAZKEPA in Europe); beliefs about icosapent ethyl (IPE)'s role concerning appropriate patients suffering from cardiovascular disease (CVD) and potential population health impact, 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 2023. 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

Investors and others should note that Amarin communicates with its investors and the public using the company website (www.amarincorp.com) and the investor relations website (www.amarincorp.com/investor-relations), 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.

Amarin Contact Information

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¹ Bhatt DL, Steg PG, Brinton E, et al., on behalf of the REDUCE-IT Investigators. Rationale and Design of REDUCE-IT: Reduction of Cardiovascular Events with Icosapent Ethyl–Intervention Trial. *Clin Cardiol*. 2017;40:138-148.

² Bhatt DL, Steg PG, Miller M, et al., on behalf of the REDUCE-IT Investigators. Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglyceridemia. *N Engl J Med*. 2019;380:11-22.