Latest Research Evaluating VASCEPA®/VAZKEPA® (icosapent ethyl) and Subgroups from the REDUCE-IT Landmark Outcomes Trial to be Presented at the American Heart Association (AHA) Scientific Sessions 2023

October 26, 2023

-- Additional Mechanistic Data on Eicosapentaenoic Acid (EPA) and Real-World Characteristics of Patients with Diabetes on IPE Also Featured at the Meeting --

DUBLIN, Ireland and BRIDGEWATER, N.J., Oct. 26, 2023 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) today announced new supported and/or funded research from the landmark REDUCE-IT cardiovascular outcomes trial on the effects of VASCEPA®/VAZKEPA® (icosapent ethyl) in a specific patient subgroups at increased risk of a cardiovascular (CV) event has been accepted for presentation at the American Heart Association (AHA) Scientific Sessions 2023, taking place November 11 – 13, 2023 in Philadelphia, PA.

The accepted abstracts include a presentation on the reduction in first and total CV events following treatment with VASCEPA/VAZKEPA in a unique, high-risk patient subgroup with a history of Metabolic Syndrome at baseline, but without diabetes. This subgroup was almost exclusively comprised of patients with established cardiovascular disease. In addition, data from mechanistic analyses will be presented providing additional insights into Eicosapentaenoic Acid (EPA) and Docosahexaenoic Acid (DHA) and their differential effects in model lipid membranes as well as the effects of EPA on oxidation of Lp(a) enriched plasma. Lastly, an abstract describing the demographic/clinical characteristics of US patients taking icosapent ethyl, focusing on those with diabetes, will also be presented. These and other new findings will be presented by a variety of international academic collaborators based on research or analyses supported by Amarin.

Nabil Abadir, MB. CH.B., SVP, Chief Medical Officer, and Head of Global Medical Affairs at Amarin, commented on the data being presented at the meeting, stating, "The data being presented at Scientific Sessions continue to further validate the overall results of the REDUCE-IT trial and the added value of VASCEPA/VAZKEPA for patients. With these data we now have more insights into patients with a history of Metabolic Syndrome at baseline, including those secondary prevention patients with established cardiovascular disease, a patient group particularly at high-risk of having another cardiovascular event. Additionally, we are pleased to support data being featured at the meeting highlighting the characteristics of patients with diabetes who were put on IPE in a real world setting as well as data that continue to illuminate the mechanism of action underlying the icosapent ethyl molecule."

“This latest research reaffirms Amarin's commitment to advancing cardiovascular care and highlights the potential benefits of VASCEPA®/VAZKEPA® in improving the health and well-being of patients at increased risk of cardiovascular events,” concluded Abadir.

Featured Amarin-supported abstracts to be presented at AHA Scientific Sessions 2023 include:

Oral Presentation

- **Effectiveness of Icosapent Ethyl on First and Total Cardiovascular Events in the Metabolic Syndrome: REDUCE-IT MetSyn**

Michael Miller, Deepak L. Bhatt, Eliot A. Brinton, Terry A Jacobson et al...

– Available November 12th, 9-9:10 am

Poster Presentations

- **Cross-Sectional Analysis of Demographic and Clinical Characteristics of Patients Using Icosapent Ethyl, With a Focus on Patients With Diabetes**

Om P Ganda, Peter P Toth, Handrean Soran, et al...

- Available November 12th, 11:30-12:45 pm

- Zone 3, Science and Technology Hall, Level 2

- **Eicosapentaenoic Acid Inhibits Lipoprotein(a) With Higher Rates of Oxidation Compared to Non-Modified Low-Density Lipoprotein In Vitro**

Preston Mason, Samuel CR Sherratt, Peter Libby, et al…

– Available November 11th, 11:30-12:45 pm

- Zone 1, Science and Technology Hall, Level 2

- **Eicosapentaenoic Acid (EPA) and Docosahexaenoic Acid (DHA) have Competing Effects on Membrane Lipid Dynamics due to Differences in Structure**
  Preston Mason, Samuel C.R. Sherratt, Sandeep Shrivastava, et al... – Available November 11th, 11:30-12:45 pm

- Zone 1, Science and Technology Hall, Level 2

About Amarin

Amarin is an innovative pharmaceutical company leading a new paradigm in cardiovascular disease management. From our foundation in scientific research 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, Zug in Switzerland, and other countries in Europe as well as commercial partners and suppliers around the world. We are committed to increasing the scientific understanding of the cardiovascular risk that persists beyond traditional therapies and advancing the treatment of that risk.

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 ≥3% and ≥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.

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 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 communicates with its investors and the public using the company website (www.amarincorp.com) and the investor relations website (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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