Latest Research Evaluating Clinical Benefits of VASCEPA®/VAZKEPA® (icosapent ethyl) to be Presented at the European Society of Cardiology (ESC) Congress

July 26, 2023

DUBLIN, Ireland and BRIDGEWATER, N.J., July 26, 2023 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) today announced the acceptance of funded research for presentation at the European Society of Cardiology (ESC) Congress, both onsite and online in Amsterdam, August 25-28, 2023. This new research includes, along with other topics, the review of the contribution of eicosapentaenoic acid (EPA) and other biomarkers to MACE reduction by icosapent ethyl (IPE).

The accepted abstracts will be presented by international academic collaborators, including Dr. Deepak L. Bhatt MD, MPH, Director of Mount Sinai Heart and the Dr. Valentin Fuster Professor of Cardiovascular Medicine, based on research or analyses sponsored by Amarin.

Featured Amarin-supported abstracts to be presented at ESC Congress 2023 include:

Abstract Sessions Oral Presentation

- *Session: Remnant cholesterol and triglyceride-rich lipoproteins in atherosclerosis progression and cardiovascular disease*

Eicosapentaenoic Acid, Arachidonic Acid, and Triglyceride Levels Mediate Most of the Benefit of Icosapent Ethyl in REDUCE-IT

Michael Szarek PhD, Deepak L. Bhatt, MD, MPH, Michael Miller, MD, et al.

-Available: August 26 at 9:24 CET (3:24 a.m. EST) in Lisbon Room

- *Session: What's new in lipid lowering?*

Effects of Icosapent Ethyl On Residual Cardiovascular Risk According To Predicted Baseline Risk: Results From REDUCE-IT

Pascal M. Burger, Deepak L. Bhatt, Jannick A.N. Dorresteijn, Ph. Gabriel Steg, et al.

-Available: August 27 at 11:05 CET (5:05 a.m. EST) in Science Box 2

Moderated Poster Presentation

- *Session: Hypertriglyceridemia treatment: CEPT, icosapent ethyl, and fibrates*

Cross-Sectional Analysis of Demographic and Clinical Characteristics of Patients Using Icosapent Ethyl

John R. Nelson, MD, Peter P. Toth, MD, PhD, Handrean Soren, MSc, MD, et al.

-Available: August 27 at 16:15 CET (10:14 a.m. EST) in Station 9

“We continue to be encouraged by new data generated and presented at ESC 2023 which continues to validate and underscore the clinical and therapeutic value of IPE and VASCEPA/VAZKEPA for clinicians and tens of millions of patients globally,” said Nabil Abadir, MB. CH.B., SVP, Chief Medical Officer and Head of Global Medical Affairs, Amarin. “These data provide additional evidence for clinicians to make the best therapeutic choice possible for their patients and should bolster confidence in VASCEPA/VAZKEPA as a proven treatment option on top of statins to reduce CV risk and to help optimize treatment in appropriate high-risk patients. We are proud of the continued work that is being done to enhance the proven efficacy of VASCEPA/VAZKEPA 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. 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 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.[i] 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%.[ii]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.[iii],[iv],[v]

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.[vi] The primary results of REDUCE-IT were published in The New England Journal of Medicine in November 2018.[vii] The total events results of REDUCE-IT were published in the Journal of the American College of Cardiology in March 2019.[viii] These and other publications can be found in the R&D section on the company's website at **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 (≥500 mg/dL) hypertriglyceridemia. Since launch, VASCEPA has been prescribed more than 20 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, 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. VAZKEPA is being commercialized in multiple European countries, including England, Wales, Sweden and Finland.

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 (≥ 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**.

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 how the data generated and presented at ESC 2023 helps validate and underscore the clinical and therapeutic value of icosapent etyhl (IPE) and VASCEPA/VAZKEPA for clinicians and millions of patients globally; and the overall potential and future success of VASCEPA/VAZKEPA and Amarin 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 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

Amarin communicates with its investors and the public using the company website (www.amarincorp.com) and the investor relations website (amarincorp.gcs-web.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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[i] American Heart Association. Heart Disease and Stroke Statistics—2020 Update: A Report From the American Heart Association.*Circulation*. 2020;141:e139-e596.

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[iv] Toth PP, Granowitz C, Hull M, et al. High triglycerides are associated with increased cardiovascular events, medical costs, and resource use: A real-world administrative claims analysis of statin-treated patients with high residual cardiovascular risk. *J Am Heart Assoc*. 2018;7(15):e008740.

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