New REDUCE-IT® Data Show VASCEPA®/VAZKEPA® (icosapent ethyl) Reduced STEMI as Well as Other MI Subtypes

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-- Late-Breaking Data Show VASCEPA/VAZKEPA Significantly Reduced STEMI by 40% and NSTEMI by 27% in Pre-Specified, Post Hoc Analyses --

-- Data Presented During Late-Breaking Science Session at European Society of Cardiology (ESC) Congress 2022 in Barcelona --

DUBLIN, Ireland and BRIDGEWATER, N.J., Aug. 26, 2022 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) today announced that new REDUCE-IT data show that VASCEPA/VAZKEPA (icosapent ethyl) significantly reduced ST-segment elevation myocardial infarction (STEMI), non-ST segment elevated myocardial infarction (NSTEMI), and other MI subtypes in patients with established cardiovascular disease (CVD) or diabetes with risk factors.

The REDUCE-IT data presented today show STEMI was significantly reduced by 40% following treatment with icosapent ethyl (IPE) compared to placebo. IPE also significantly reduced NSTEMI by 27%. These data were presented today during a Late-Breaking Science Session at the European Society of Cardiology (ESC) Congress 2022 in Barcelona, Spain.

“This analysis of REDUCE-IT clearly shows that IPE 4 g/day as an adjunct to statin therapy in high-risk patients with residual hypertriglyceridemia provides a large and significant reduction in heart attacks,” said Deepak L. Bhatt, M.D., M.P.H., Executive Director of Interventional Cardiovascular Programs at Brigham and Women’s Hospital, Professor of Medicine at Harvard Medical School, and principal investigator of the REDUCE-IT trial. “Importantly, these new data show a significant reduction in the most important type of heart attack known as STEMI, as well as other MI subtypes.”

The REDUCE-IT study randomized 8,179 adult statin-treated patients with elevated triglycerides and either established CV disease or diabetes plus risk factors to IPE or placebo; median follow-up was 4.9 years. IPE treatment reduced the primary composite endpoint (CV death, nonfatal myocardial infarction [MI], nonfatal stroke, coronary revascularization, or hospitalization for unstable angina) and key secondary composite endpoint (CV death, nonfatal MI, or nonfatal stroke) endpoints 25% and 26%, respectively. Prespecified and post hoc analyses examined MI subtypes, which were independently adjudicated by a blinded Clinical Endpoint Committee.

In time to first event analyses, MI was significantly reduced with IPE treatment (HR=0.69; 95% CI 0.58, 0.81; P<0.0001) with a number needed to treat (NNT) of 39. IPE significantly reduced STEMI (HR=0.60; 95% CI 0.44, 0.81; P=0.0008) and NSTEMI (HR=0.73; 95% CI 0.60, 0.89; P=0.001). There were clinically important and statistically significant reductions in MI subtypes, including MI leading to cardiac arrest (HR=0.49; 95% CI 0.28, 0.87; P=0.01) and resuscitated MI (HR=0.34; 95% CI 0.15, 0.76; P=0.006). IPE also significantly reduced the overall burden of total (first and subsequent) STEMI (rate ratio [RR]=0.59; 95% CI 0.43, 0.80; P=0.0006) and total NSTEMI (RR=0.72; 95% CI 0.58, 0.88; P=0.002) versus placebo.

All analyses highlighted above were funded by Amarin. Dr. Bhatt received research funding paid to Brigham and Women’s Hospital from Amarin for his role as the Chair of REDUCE-IT.

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.[1] 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%.[2] 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.[3,4,5]

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.[6] The primary results of REDUCE-IT were published in The New England Journal of Medicine in November 2018.[7] The total events results of REDUCE-IT were published in the Journal of the American College of

Cardiology in March 2019.[8] 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 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 (≥ 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 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) and the investor relations website (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

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