Latest Clinical Research Evaluating VASCEPA®/VAZKEPA (Icosapent Ethyl) in Patients with Residual Cardiovascular Risk to be Presented at ESC Congress 2021, Organized by the European Society of Cardiology

August 16, 2021

Amarin-Supported Research and Analyses from International Academic Collaborators to Be Featured in Seven Presentations

DUBLIN, Ireland and BRIDGEWATER, N.J., Aug. 16, 2021 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) today announced that new data that add to the growing body of knowledge on VASCEPA®/VAZKEPA (icosapent ethyl) in patients at risk for major adverse cardiovascular events will be presented at ESC Congress 2021, organized by the European Society of Cardiology (ESC), being held virtually from August 27 – August 30, 2021. These and other new findings will be presented in two Late-Breaking Science presentations and five e-Poster presentations from a variety of international academic collaborators based on research or analyses supported by Amarin.

"Given the growing global burden of cardiovascular disease, we are pleased that new data is being presented at this year's ESC Congress in support of the clinical efficacy and underlying scientific rationale for VASCEPA/VAZKEPA to address residual cardiovascular risk. These presentations are particularly timely as we will soon initiate our European launch, starting in Germany, and these data amplify the potential for VASCEPA/VAZKEPA to address heart health in at-risk patients," said Karim Mikhail, Amarin's president and chief executive officer. "We are also looking forward to the first readout from PREPARE-IT 1, part of a larger investigator-initiated study program, looking at the potential benefits of VASCEPA/VAZKEPA for the prevention of COVID-19 in people at risk of exposure to the infection. With COVID-19 continuing to spread due to variants as well as low vaccine rates globally, these data could provide valuable insights in the ongoing fight against this pandemic."

Featured Amarin-supported abstracts to be presented at ESC Congress 2021 include:

Late-Breaking Science Presentations

- *Session: Late-Breaking Science*
  "Reduction in Ischemic Events, Including Cardiovascular Mortality, with Icosapent Ethyl in Patients with Prior Myocardial Infarction: REDUCE-IT PRIOR MI" – presented on behalf of all authors by Deepak L. Bhatt, M.D., M.P.H., Brigham and Women's Hospital – Available On-Demand from August 23, 9:00 a.m. CEST

- *Session: Late-Breaking Trials-COVID-19*
  "Icosapent Ethyl Versus Placebo in People Exposed to COVID-19: The Main Results of PREPARE-IT-1" – presented on behalf of all authors by Rafael Diaz, M.D., Estudios Cardiologicos Latinoamerica (ECLA), Rosario, Argentina – August 29, 2:00 p.m. CEST

e-Poster Presentations

- *Session: Preventive Cardiology and Special Populations*
  "Cardiovascular benefits outweigh risks in patients with atrial fibrillation in REDUCE-IT (Reduction of Cardiovascular Events with Icosapent Ethyl-Intervention Trial)" – presented on behalf of all authors by Brian Olshansky, M.D., University of Iowa – Available On-Demand from August 23, 9:00 a.m. CEST

- *Session: e-Posters*
  "**Omega-3 Fatty Acids Differentially Alter the Expression of Detoxification Enzymes and Nitric Oxide Bioavailability in Endothelial Cells during IL-6 Exposure"** – presented on behalf of all authors by R. Preston Mason, Ph.D., Brigham and Women's Hospital – Available On-Demand from August 23, 9:00 am CEST

- *Session: e-Posters*
  "Omega-3 Fatty Acids Differentially Reduced Expression of Neutrophil Degranulation-Associated Proteins in Endothelial Cells during IL-6 Exposure" – presented on behalf of all authors by R. Preston Mason, Ph.D., Brigham and Women's Hospital – Available On-Demand from August 23, 9:00 am CEST

- *Session: e-Poster*
  "Eicosapentaenoic Acid Inhibits Lipopolysaccharide (LPS)-induced Nitrite Production and Cytokine Release from J774 Macrophages" presented on behalf of all authors by R. Preston Mason, Ph.D., Brigham and Women's Hospital – Available On-Demand from August 23, 9:00 am CEST

- *Session: e-Poster*
  "**Characteristics and prognosis of patients with elevated triglycerides in acute myocardial infarction: observational data from a large database over a 17-years period" –** presented on behalf of all authors by Michel Farnier, M.D.,

University of Bourgogne Franche Comte - Dijon, France – Available On-Demand from August 23, 9:00 am CEST

Additional REDUCE-IT® and icosapent ethyl (EPA)-related topics will be presented at ESC Congress 2021 and can be found at https://digital-congress.escardio.org/ESC-Congress (if registered to ESC Congress).

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® (icosapent ethyl) Capsules

VASCEPA (icosapent ethyl) capsules are the first-and-only 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 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 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, 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.

Key clinical effects of VASCEPA on major adverse cardiovascular events are included in the Clinical Studies section of the prescribing information for VASCEPA as set forth below:

Effect of VASCEPA on Time to First Occurrence of Cardiovascular Events in Patients with Elevated Triglyceride levels and Other Risk Factors for Cardiovascular Disease in REDUCE-IT

	VASCEPA		Placebo		VASCEPA vs Placebo
	N = 4089 n (%)	Incidence Rate (per 100 patient years)	N = 4090 n (%)	Incidence Rate (per 100 patient years)	Hazard Ratio (95% CI)
Primary composite endpoint					
Cardiovascular death, myocardial infarction, stroke, coronary revascularization, hospitalization for unstable angina (5-point MACE)	705 (17.2)	4.3	901 (22.0)	5.7	0.75 (0.68, 0.83)
Key secondary composite endpoint					
Cardiovascular death, myocardial infarction, stroke (3-point MACE)	459 (11.2)	2.7	606 (14.8)	3.7	0.74 (0.65, 0.83)
Other secondary endpoints					
Fatal or non-fatal myocardial infarction	250 (6.1)	1.5	355 (8.7)	2.1	0.69 (0.58, 0.81)
Emergent or urgent coronary revascularization	216 (5.3)	1.3	321 (7.8)	1.9	0.65 (0.55, 0.78)
Cardiovascular death [1]	174 (4.3)	1.0	213 (5.2)	1.2	0.80 (0.66, 0.98)
Hospitalization for unstable angina [2]	108 (2.6)	0.6	157 (3.8)	0.9	0.68 (0.53, 0.87)
Fatal or non-fatal stroke	98 (2.4)	0.6	134 (3.3)	0.8	0.72 (0.55, 0.93)

[1] Includes adjudicated cardiovascular deaths and deaths of undetermined causality.
[2] Determined to be caused by myocardial ischemia by invasive/non-invasive testing and requiring emergent hospitalization.

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, including statements regarding the potential impact of VASCEPA in various clinical uses. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: uncertainties associated generally with research and development and clinical trials such as further clinical evaluations failing to confirm earlier findings. 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 its most recent Quarterly Report on Form 10-Q. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Amarin undertakes no obligation to update or revise the information contained in this press release, 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), the investor relations website (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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