Amarin Reports Overview of Latest Clinical Research Evaluating VASCEPA®/VAZKEPA (Icosapent Ethyl) and Eicosapentaenoic Acid (EPA) Presented at ESC Congress 2021, Organized by the European Society of Cardiology

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VASCEPA/VAZKEPA found in prespecified and post hoc analyses to reduce first and total primary endpoints by 26% and 35%, respectively, in REDUCE-IT patients with prior Myocardial Infarction

2021 ESC Guidelines on Cardiovascular Disease Prevention now include VAZKEPA in their recommendations, marking 20th inclusion in global medical societies' guidelines

DUBLIN, Ireland and BRIDGEWATER, N.J., Aug. 31, 2021 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) today reported an overview of new data relating to VASCEPA®/VAZKEPA (icosapent ethyl) presented at ESC Congress 2021, organized by the European Society of Cardiology (ESC), taking place virtually from August 27 – August 30, 2021.

"We are delighted to have this collection of data in support of VASCEPA/VAZKEPA's differentiated positioning in treating patients at risk for major adverse cardiovascular events presented at ESC 2021 before an audience of global cardiovascular specialists," said Karim Mikhail, Amarin's president and chief executive officer. "As we approach the European launch of VAZKEPA, it is particularly important that such clinical and scientific findings are reported. Collectively, these data are building a body of clinical evidence that elucidate and evolve our understanding of the potential mechanisms of action and supporting role of the therapy in alleviating the burden of the worldwide public health crisis caused by cardiovascular disease."

ESC 2021 Guidelines on Cardiovascular Disease Prevention in Clinical Practice

Amarin also reports that the ESC released their 2021 Guidelines on cardiovascular disease prevention in clinical practice, which includes icosapent ethyl (VAZKEPA) as a new recommendation to address high-risk cardiovascular patients with elevated triglycerides (135-499 mg/dL) despite statin treatment and lifestyle measures. The classification is a Level B recommendation, which reflects a relatively high weight of scientific evidence under ESC standards. This guideline was developed by the Task Force for cardiovascular disease prevention in clinical practice with representatives of the ESC and 12 medical societies with the special contribution of the European Association of Preventive Cardiology (EAPC). With this new inclusion, VASCEPA/VAZKEPA is now included in 20 separate guidelines, scientific statements, or consensus statements.

"The expanding inclusion of VASCEPA/VAZKEPA in global clinical practice guidelines further validates the important role our IPE plays in addressing cardiovascular risk. This new inclusion in the ESC guidelines is particularly timely as we are planning our initial country launch in Europe in September," added Mr. Mikhail.

Key data presented at ESC Congress 2021

Late Breaking Science Presentations

"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.

Highlights: The investigators concluded that, "Icosapent ethyl 4 g/day significantly reduced first and total primary endpoints of 5-point major adverse cardiovascular event (MACE), comprised of CV death, MI (myocardial infarction), stroke, coronary revascularization, and hospitalization for unstable angina by 26% and 35%, respectively, in REDUCE-IT patients with prior MI (P=0.00001 and P=0.0000001, respectively). Icosapent ethyl led to generally robust reductions across the prespecified hierarchy of secondary endpoints, and in sudden cardiac death and cardiac arrest. The benefits of icosapent ethyl in patients with prior MI were consistent in those with or without a history or prior revascularization."

For more information on this Late Breaking Science session, see Amarin's previously issued press release, which is available here.

"Icosapent Ethyl (IPE) 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.

Highlights: These data represent the first presentation of the topline final results from the PREPARE-IT 1 study, which was an investigator-initiated trial (IIT) of approximately 2000 SARS CoV-2 negative, high-risk healthcare and other public workers in Argentina. In this study, subjects were randomized 1:1 to receive IPE or placebo and received a loading dose of 8 grams per day on days 1-3 and 4 grams per day on days 4-60. The primary endpoint is the percentage of subjects positive for SARS-CoV-2 through day 60.

While the results of the PREPARE-IT 1 study in Argentina did not meet the primary and/or other endpoints studied, we believe it is valuable for Amarin to support pilot investigator-initiated trials (IITs) of this nature to determine the safety and potential efficacy of VASCEPA/VAZKEPA (icosapent ethyl) in a diverse group of at-risk populations.

PREPARE-IT 1 is part of a series of IITs evaluating VASCEPA's potential benefit in preventing and/or treating COVID-19. Amarin is looking forward to the results of the PREPARE-IT 2 and MITIGATE trials, as the totality of the data will advise the various clinical and regulatory pathways Amarin may explore for the potential use of VASCEPA as an adjunctive treatment to reduce the risk of infection and/or as a treatment for COVID-19.

The results of this study have no relationship to or bearing on the FDA-approved indication for VASCEPA to reduce CV risk when added to a statin.

e-Poster Presentations

"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.

Highlights: *Post hoc* analyses of REDUCE-IT subgroups with baseline atrial fibrillation and/or flutter (AF/F) history or in-study endpoints of AF/F hospitalization evaluated subjects with prior baseline AF/F history identified from medical history. In-study AF/F was included within a broader prespecified adjudicated endpoint of "cardiac arrhythmia requiring hospitalization ≥24 hours," under which the type of arrhythmia (e.g., AF/F) was specified. AF/F events not meeting endpoint criteria remained in the safety data set.

The study authors concluded that, when treated with icosapent ethyl (IPE), REDUCE-IT patients with atrial fibrillation history or in-study atrial fibrillation hospitalization endpoints had greater CV risk, but similar relative risk reduction in primary, key secondary, and fatal or nonfatal stroke endpoints.

"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.

Highlights: Endothelial cell (EC) dysfunction is causally related to abnormal vasodilation and contributes to increased risk for atherothrombotic disease. Hallmark features of EC dysfunction include reduced nitric oxide (NO) bioavailability and increased production of the cytotoxic peroxynitrite anion (ONOO-) as a result of nitic oxide synthase (eNOS) uncoupling and oxidative stress. This study compared the effects of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) on endothelial function and detoxification enzyme expression under conditions of inflammation with IL-6.

The study concluded that, "EPA and DHA differentially influenced NO bioavailability and expression of ROS (reactive oxygen species) detoxification proteins, including peroxiredoxin and superoxide isoforms. The net benefits of EPA on eNOS function and free radical detoxification may contribute to reduced atherothrombotic risk compared to DHA."

"Omega-3 Fatty Acids Differentially Reduce 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.

Highlights: It has been shown that when challenged with pro-inflammatory stimuli, endothelial cells can produce signals (IL-6) that induce neutrophil degranulation. The goal of this study was to use proteomic approaches to compare the effects of EPA and DHA on protein expression mediating the neutrophil degranulation pathway, including platelet endothelial cell adhesion molecule 1 (PECAM 1), as determined by gene set enrichment analysis (GSEA).

The study results showed that "EPA and DHA differentially modulated expression of proteins linked to neutrophil degranulation. The distinct effects of EPA on protein expression may contribute to reduced inflammation associated with atherosclerosis compared to DHA."

"Eicosapentaenoic Acid (EPA) 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.

Highlights:
The study concluded that EPA reduced macrophage activation in a dose-dependent manner as evidenced by decreased nitrite production and cytokine release similar to other anti-inflammatory agents, and that "these findings indicate a novel effect of EPA on mechanisms of inflammation associated with vascular disease."

"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-Comté - Dijon, France.

Highlights: Using a large database of a regional registry, the study authors aimed to address the prevalence, characteristics and prognosis of patients with elevated triglycerides (TG) hospitalized for an acute myocardial infarction (MI). From the multicenter database (RICO survey), all consecutive patients hospitalized for an acute MI (2001-2017) and alive at discharge were included. Patients with TG > 500 mg/dL, lost to follow-up (FU), or under chronic fibrate treatment were excluded. Patients with high TG (> 200 mg/dL) on admission were compared to those with TG ≤ 200 mg/dL. Endpoints were recurrent ischemic events (i.e., recurrent MI, angina, unstable angina, stroke or urgent revascularization (PCI or CABG)) at 1-year FU.

The study results from this large population-based cohort showed that "elevated TG are common in acute MI, and associated with residual risk of recurrent ischemic events, beyond traditional prognostic markers. These data may help to identify candidates for targeted therapies to reduce recurrent ischemic risk after MI."

All analyses highlighted above were supported or funded by Amarin.

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 which are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including beliefs about the world-wide market potential for VASCEPA; expectations regarding financial metrics and performance such as prescription growth, revenue growth, operating expenses, inventory purchases, and managed care coverage for VASCEPA, including the impact of the COVID-19 pandemic, the disappointing outcome of patent litigation and the launch of generic competition on these metrics; beliefs that Amarin is well positioned to deliver on its goals to grow VASCEPA in the U.S. and beyond; beliefs about patient needs for VASCEPA; effects of the COVID-19 pandemic on Amarin's operations and on the healthcare industry more broadly, which effects continue to be fluid; beliefs that Amarin's strategy for reducing the effects of cardiovascular disease is sound and that Amarin is efficiently reaching physicians, payors, pharmacists and patients; plans for Amarin's go-to-market model; the timing and outcome of regulatory reviews, recommendations and approvals and related reimbursement decisions and commercial launches in Europe, the China region and elsewhere; plans for Amarin's expected launch of VASCEPA directly in major markets in Europe, directly and indirectly; beliefs about the cardioprotective and other benefits of VASCEPA; beliefs about the strength of data in market access dossiers and other reports; expectations for the timing, effectiveness and outcome of promotional activities, including patient-oriented campaigns, conference and posted presentations and education of healthcare professionals; commercial and international expansion, prescription growth and revenue growth and future revenue levels, including the contributions of sales representatives and the new leadership team; beliefs that Amarin's current resources are sufficient to fund projected operations; ongoing patent litigation efforts; and the impact of the COVID-19 pandemic on all of the forgoing. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. Amarin's ability to effectively commercialize VASCEPA and maintain or grow market share will depend in part on Amarin's ability to continue to effectively finance its business, VASCEPA approval in geographies outside the U.S., efforts of third parties, Amarin's ability to create and increase market demand for VASCEPA through education, marketing and sales activities, to achieve broad market acceptance of VASCEPA, to receive adequate levels of reimbursement from third-party payers, to develop and maintain a consistent source of commercial supply at a competitive price, to comply with legal and regulatory requirements in connection with the sale and promotion of VASCEPA and to secure, maintain and defend its patent protection for VASCEPA. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: the possibility that VASCEPA may not receive regulatory approval in the China region or other geographies on the expected timelines or at all, the risk that additional generic versions of VASCEPA will enter the market and that generic versions of VASCEPA will achieve greater market share and more commercial supply than anticipated, particularly in light of the recent and disappointing outcome of Amarin's litigation against two generic drug companies and subsequent requests for appeal; the risk that the scope and duration of the COVID-19 pandemic will continue to impact access to and sales of VASCEPA; the risk that Amarin has overestimated the market potential for VASCEPA in the U.S., Europe and other geographies; risks associated with Amarin's expanded enterprise; uncertainties associated generally with research and development, clinical trials and related regulatory approvals; the risk that sales may not meet expectations and related cost may increase beyond expectations; the risk that patents may be determined to not be infringed or not be valid in patent litigation and applications may not result in issued patents sufficient to protect the VASCEPA franchise. 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 quarterly report on Form 10-Q for the quarter ended June 30, 2021, filed on or about the date hereof. 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), 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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