



New REDUCE-IT® Analyses Presented at ESC 2025 Include Data Showing VASCEPA®/VAZKEPA® (Icosapent Ethyl) Therapy Resulted in 9% Fewer Total Hospitalizations & Reduces Cardiovascular Disease Risk in Certain High-Risk Patient Subgroups

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-- 2025 ESC/EAS Dyslipidemia Guideline Focused Update Reaffirms High Dose Icosapent Ethyl as Class IIA Recommended Therapy in High-Risk or Very High-Risk Patients Based on REDUCE-IT --

DUBLIN and BRIDGEWATER, N.J., Aug. 30, 2025 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) today highlighted three sub-analyses from the REDUCE-IT® trial describing the impact of VASCEPA®/VAZKEPA® (icosapent ethyl - IPE) administration on cardiovascular disease (CVD) risk associated with Cardiovascular-Kidney-Metabolic (CKM) syndrome, major adverse cardiovascular events (MACE) stratified by baseline apolipoprotein B (ApoB) and fasting triglyceride rich lipoprotein cholesterol (TRL-C) levels, and on hospitalizations. All three post hoc analyses showed significant reductions in cardiovascular risk and outcomes in the populations studied. The data was presented at the European Society of Cardiology (ESC) Congress 2025 in Madrid, Spain.

"The REDUCE-IT data continue to yield important insights into the clinical utility of VASCEPA/VAZKEPA and how icosapent ethyl can reduce cardiovascular risk across diverse patient populations," said Deepak L. Bhatt, MD, MPH, MBA, Director of Mount Sinai Fuster Heart Hospital. "These new analyses reinforce the robustness of the original findings and highlight the potential of icosapent ethyl to address complex conditions like cardiovascular-kidney-metabolic syndrome and lipid-driven risk. The consistency of benefit observed across multiple high-risk subgroups supports its integration into contemporary treatment strategies as a complementary therapy aimed at improving patient outcomes."

Key findings from these post hoc analyses are outlined below:

Icosapent Ethyl Reduces CVD Risk in Cardiovascular-Kidney-Metabolic Syndrome: REDUCE-IT CKM

Cardiovascular-kidney-metabolic syndrome is a recently defined disorder linking metabolic syndrome risk factors to chronic kidney disease and cardiovascular disease.

This analysis examined the incremental CVD risk of CKM in secondary prevention patients with metabolic syndrome but without diabetes at baseline (n=2860) and the effect of IPE therapy. Subjects were divided into four baseline estimated glomerular filtration rate (eGFR) groups: ≥ 90 , < 90 , ≥ 60 , and < 60 mL/min/1.73 m². IPE treatment vs placebo showed a statistically significant reduction in the primary composite endpoint (CV death, nonfatal MI, nonfatal stroke, coronary revascularization, or unstable angina) in eGFR groups < 60 , ≥ 60 , and < 90 . IPE treatment in the eGFR < 60 group showed a 44% relative risk reduction (RRR) for time to the first primary composite endpoint, hazard ratio (HR) 0.56 (95% CI 0.39, 0.79), $P = 0.001$, absolute risk reduction (ARR) = 11.2%, number needed to treat (NNT) = 9.

The analysis showed that IPE treatment reduced CVD risk in patients with CKM syndrome, thereby supporting a role for this therapy in these high CVD risk patients.

Icosapent Ethyl Reduces Cardiovascular Risk Across Apolipoprotein B and Fasting Triglyceride Rich Lipoprotein Levels

Increased ApoB levels due to triglyceride rich lipoproteins (TRL) are associated with increased cardiovascular risk, even when low-density lipoprotein cholesterol (LDL-C) levels are well controlled.

This analysis assessed the impact of IPE on MACE (CV death, nonfatal MI, nonfatal stroke, coronary revascularization, or unstable angina) stratified by ApoB and fasting TRL-C. Relationships between quartiles of baseline ApoB concentration, baseline fasting TRL-C and risk for first MACE were analyzed.

IPE treatment resulted in significant reductions in MACE, from the first through fourth baseline quartiles of ApoB: HR 0.72 (95% CI 0.58, 0.88), HR 0.73 (95% CI 0.59, 0.89), HR 0.76 (95% CI 0.63, 0.91), and HR 0.80 (95% CI 0.66, 0.97), respectively, all $P \leq 0.02$. Additionally, there were significant reductions in MACE from the second through fourth baseline quartiles of TRL-C: HR 0.74 (95% CI 0.60, 0.90), HR 0.79 (95% CI 0.65, 0.96), and HR 0.68 (95% CI 0.56, 0.82), respectively, all $P \leq 0.02$.

This analysis showed that IPE significantly reduced MACE across all quartiles of baseline ApoB and TRL-C concentrations above the 25th percentile, supporting the use of IPE in patients with mild or moderate hypertriglyceridemia regardless of ApoB and TRL-C levels.

Effects of Icosapent Ethyl on Risk and Duration of Hospitalizations and Death in REDUCE-IT

This analysis of REDUCE-IT estimated the effects of IPE treatment on total hospitalizations and days lost to hospitalization and death.

The analysis showed that among participants in REDUCE-IT, IPE reduced total hospitalizations and had favorable impacts on measures of days lost due to hospitalization and death. IPE significantly reduced total hospitalizations, HR 0.91 (95% CI 0.84, 0.98), $P=0.017$; increased the likelihood of surviving until end of study without hospitalization, odds ratio (OR) 1.12 (95% CI 1.02, 1.22), $P=0.016$; and had a lower rate of days lost among those who were hospitalized and/or died during follow-up, rate ratio (RR) 0.93 (95% CI 0.93, 0.94), $P<0.001$.

These findings provide additional insights on the effects of IPE on patient-centered measures of total disease burden.

Recommendation for High Dose Icosapent Ethyl Reaffirmed in ESC/EAS Dyslipidemias Guideline Focused Update as Class IIA Therapy in High-Risk or Very High-Risk Patients to Reduce Cardiovascular Events

In addition to the abstracts presented at ESC, use of icosapent ethyl was reaffirmed as a Class IIA recommendation within the ESC/EAS Dyslipidemias Guideline Focused Update. The guideline states, “that high-dose icosapent ethyl (as in the REDUCE-IT trial) should be considered for high-risk or very high-risk patients with elevated triglyceride levels (fasting triglyceride level 135–499 mg/dL [1.52–5.63 mmol/L]) despite statin therapy to lower CVD events.” “We were very pleased to see the maintenance of IPE class recommendation in this ESC/EAS focused dyslipidemia update based on our robust data from REDUCE-IT,” said Steven Ketchum, Ph.D., EVP, President of R&D, and Chief Scientific Officer at Amarin. “The focused update also states that, in contrast to the robust evidence of ASCVD risk reduction with LDL-C lowering therapies, the efficacy of triglyceride lowering with fibrates in reducing ASCVD risk has not been established, and that there has not been evidence that dietary supplementation with polyunsaturated fatty acids, including EPA+DHA mixtures, can lower LDL-C levels or reduce the risk of CV events.”¹

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. Amarin provided funding to Mount Sinai Hospital for Dr. Bhatt's work on the above analyses.

About VASCEPA®/VAZKEPA® (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 twenty-five million times. VASCEPA is covered by most major medical insurance plans. In addition to the United States, VASCEPA is approved and sold in Canada, China, Australia, Lebanon, the United Arab Emirates, Saudi Arabia, Qatar, Bahrain, and Kuwait. 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 (applying to England, Scotland and Wales). VAZKEPA (icosapent ethyl) is currently approved and sold in Europe in Sweden, Finland, England/Wales, Spain, Netherlands, Scotland, Greece, Portugal, Italy, Denmark and Austria.

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 $\geq 3\%$ and $\geq 1\%$ 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 VASKEPA® in Europe, please visit: https://www.ema.europa.eu/en/documents/product-information/vazkepa-epar-product-information_en.pdf

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 Amarin's key achievements in 2024 and the potential impact and outlook for achievements in 2025 and beyond; Amarin's 2025 financial outlook and cash position; Amarin's overall efforts to expand access and reimbursement to VASKEPA across global markets; expectations regarding potential strategic collaboration and licensing agreements with third parties, including our ability to attract additional collaborators, as well as our plans and strategies for entering into potential strategic collaboration and licensing agreements and the overall potential and future success of VASCEPA/VASKEPA and Amarin that are based on the beliefs and assumptions and information currently available to Amarin. All statements other than statements of historical fact contained in this press release are forward-looking statements. 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 quarterly report on Form 10-Q for the period ending June 30, 2025 and annual report on Form 10-K for the fiscal year ended 2024. 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. 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 (www.amarincorp.com/investor-relations) including but not limited to investor presentations and investor FAQs, U.S. Securities and Exchange Commission filings, press releases, public conference calls and webcasts.

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 (investors.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.

Amarin Contact Information

Media Inquiries:
Tegan Berry
Amarin Corporation plc
PR@amarincorp.com

Investor Inquiries:
Bob Burrows

Western Avenue Advisers LLC
Investor.relations@amarincorp.com

¹ François Mach, Konstantinos C Koskinas, Jeanine E Roeters van Lennep, Lale Tokgözoğlu, Lina Badimon, Colin Baigent, Marianne Benn, Christoph J Binder, Alberico L Catapano, Guy G De Backer, Victoria Delgado, Natalia Fabin, Brian A Ference, Ian M Graham, Ulf Landmesser, Ulrich Laufs, Borislava Mihaylova, Børge Grønne Nordestgaard, Dimitrios J Richter, Marc S Sabatine, ESC/EAS Scientific Document Group , 2025 Focused Update of the 2019 ESC/EAS Guidelines for the management of dyslipidaemias: Developed by the task force for the management of dyslipidaemias of the European Society of Cardiology (ESC) and the European Atherosclerosis Society (EAS), European Heart Journal, 2025;., ehaf190, <https://doi.org/10.1093/eurheartj/ehaf190>