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## **Real-World Data Analysis Shows That High Triglyceride Levels Are Associated With Increased Cardiovascular Events and Medical Costs**

**Higher Rates of Myocardial Infarction (Heart Attack) and Revascularization Procedures in Patients with High Triglycerides Were Drivers of the Composite Outcome**

**MACE Rate 35% Higher in Patients Who, Despite Statin Therapy, Have Elevated Triglyceride Levels**

**Cost of Health Care Nearly 15% Higher in this Higher Risk Patient Population**

BEDMINSTER, N.J. and DUBLIN, Ireland, Nov. 13, 2017 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular (CV) health, presented a real-world data analysis today revealing that patients with high triglycerides, despite controlled LDL (bad) cholesterol, were at significantly greater risk for major adverse cardiovascular events (MACE). The patients studied also incurred higher healthcare costs than those with normal triglyceride levels. The analysis was presented at the 2017 American Heart Association (AHA) Scientific Sessions in Anaheim, CA.

The study, "High Triglycerides Increase Cardiovascular Events, Medical Costs, and Resource Utilization in a Real-World Analysis of Statin-Treated Patients with High Cardiovascular Risk and Well-Controlled Low-Density Lipoprotein Cholesterol," was based on a retrospective analysis of de-identified claims. The database utilized for the analysis had millions of de-identified medical records from patient experience within a leading national information and technology-enabled health services business. The study analyzed two adult cohorts with statin use, controlled LDL-C, and with either established atherosclerotic cardiovascular disease (ASCVD) or with diabetes mellitus and additional CV risk factors: those with high triglycerides (200-499 mg/dL) and those with normal triglycerides (< 150 mg/dL), N=10,990 per cohort. The majority of patients did not have established atherosclerotic cardiovascular disease (primary prevention).

Over an average follow-up of 41 to 42 months, ASCVD patients with high TGs, as compared with the normal TG group, were at increased risk of cardiovascular outcomes after multivariable adjustment as follows:

- | 35% increased risk for myocardial infarction (95% CI 1.19-1.52)
- | 51% increased risk for coronary revascularization (95% CI 1.34-1.69)
- | 35% higher rate of occurrence of a major adverse CV event (MACE) (95% CI 1.23-1.49)

Composite outcome = nonfatal MI, nonfatal stroke, coronary revascularization, unstable angina, or CV-related mortality

In addition, the high TG cohort had nearly a 15% higher average total health care cost and 17% higher rate of occurrence of an inpatient stay over time. Both study cohorts were predominantly comprised of primary prevention patients as only 29% of subjects had established atherosclerotic cardiovascular disease. This study analyzed health data of real-world patients and was not a prospective analysis of medical intervention.

The authors of this study were Peter P. Toth, CGH Medical Center, Sterling, IL; Craig Granowitz, Amarin Pharma, Inc., Bedminster, NJ; Michael Hull, Djibril Liassou, Amy Anderson, Optum, Eden Prairie, MN; Sephy Philip, Amarin Pharma, Inc., Bedminster, NJ.

Potential limitations of real-world data analysis include the observational, retrospective nature of the study which can add to uncertainty regarding findings as compared to prospectively collected data, the potential for inaccurate recording of health events in the database and missing data which may limit the usefulness of the findings. Without further study, the extent, if any, that a biomarker such as triglyceride levels is causally related to the clinical events cannot be determined.

"These data highlight the increased cardiovascular risk and healthcare cost in subjects with high triglyceride levels despite statin use and controlled LDL-C in a real-world setting and a large sample of patient experience over multiple years," expressed Peter Toth, MD, PhD. "The ongoing REDUCE-IT cardiovascular outcomes study will prospectively determine whether treatment with Vascepa® provides benefit for high CV risk patients with persistent high triglycerides despite statin controlled LDL-C. If positive, the results of the REDUCE-IT study could provide a pragmatic care solution for the treatment

of many at-risk patients."

## About REDUCE-IT

Amarin's clinical development program for Vascepa includes a trial known as the REDUCE-IT cardiovascular outcomes study, an 8,175-patient study commenced in 2011. REDUCE-IT is the first multinational cardiovascular outcomes study evaluating the effect of prescription pure EPA therapy, or any triglyceride-lowering therapy, as an add-on to statins in patients with high cardiovascular risk who, despite stable statin therapy, have elevated triglyceride levels (150 mg/dL to 499 mg/dL). A large portion of the male and female patients enrolled in this outcomes study are anticipated to also be diagnosed with type 2 diabetes. Amarin expects that the onset of the target final primary cardiovascular event will be reached before the end of Q1 2018, with results announced before the end of Q3 2018.

Additional information on clinical studies of Vascepa can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

## About Amarin

Amarin Corporation plc is a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health. Amarin's product development program leverages its extensive experience in lipid science and the potential therapeutic benefits of polyunsaturated fatty acids. Amarin's clinical program includes a commitment to an ongoing outcomes study. Vascepa<sup>®</sup> (icosapent ethyl), Amarin's first FDA approved product, is a highly-pure, omega-3 fatty acid product available by prescription. For more information about Vascepa visit [www.vascepa.com](http://www.vascepa.com). For more information about Amarin visit [www.amarincorp.com](http://www.amarincorp.com).

## About Vascepa<sup>®</sup> (icosapent ethyl) capsules

Vascepa<sup>®</sup> (icosapent ethyl) capsules are a single-molecule prescription product consisting of the omega-3 acid commonly known as EPA in ethyl-ester form. Vascepa is not fish oil, but is derived from fish through a stringent and complex FDA - regulated manufacturing process designed to effectively eliminate impurities and isolate and protect the single molecule active ingredient. Vascepa is known in scientific literature as AMR101. Amarin has been issued multiple patents internationally based on the unique clinical profile of Vascepa, including the drug's ability to lower triglyceride levels in relevant patient populations without raising LDL-cholesterol levels.

### FDA-Approved Indication and Usage

- | Vascepa (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe ( $\geq 500$  mg/dL) hypertriglyceridemia.
- | The effect of Vascepa on the risk for pancreatitis and cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined.

### Important Safety Information for Vascepa

- | Vascepa is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to Vascepa or any of its components.
- | Use with caution in patients with known hypersensitivity to fish and/or shellfish.
- | The most common reported adverse reaction (incidence  $> 2\%$  and greater than placebo) was arthralgia (2.3% for Vascepa, 1.0% for placebo). There was no reported adverse reaction  $> 3\%$  and greater than placebo.
- | Patients receiving treatment with Vascepa and other drugs affecting coagulation (e.g., anti-platelet agents) should be monitored periodically.
- | In patients with hepatic impairment, monitor ALT and AST levels periodically during therapy.
- | Patients should be advised to swallow Vascepa capsules whole; not to break open, crush, dissolve, or chew Vascepa.
- | Adverse events and product complaints may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.

FULL VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT [WWW.VASCEPA.COM](http://WWW.VASCEPA.COM).

Vascepa has been approved for use by the United States Food and Drug Administration (FDA) as an adjunct to diet to reduce triglyceride levels in adult patients with severe ( $\geq 500$  mg/dL) hypertriglyceridemia. Nothing in this press release should be construed as promoting the use of Vascepa in any indication that has not been approved by the FDA.

## Forward-looking statements

This press release contains statements related to scientific presentations from real-world evidence and other studies. These

statements are not promises or guarantees related to the potential for favorable outcomes from the ongoing REDUCE-IT cardiovascular outcomes trial. As disclosed in filings with the U.S. Securities and Exchange Commission, Amarin's ability to effectively develop and commercialize Vascepa will depend in part on its ability to continue to effectively finance its business, efforts of third parties, its ability to create market demand for Vascepa through education, marketing and sales activities, to achieve increased 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 maintain patent protection for Vascepa. 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, clinical trials and related regulatory approvals; the risk that future legal determinations and interactions with regulatory authorities may impact Vascepa marketing and sales rights and efforts; the risk that Vascepa may not show clinically meaningful effects in REDUCE-IT or support regulatory approvals for cardiovascular risk reduction; and the risk that patents may not be upheld in anticipated patent litigation. 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.

### **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](http://www.amarincorp.com)), the investor relations website (<http://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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