Amarin Corporation

Amarin's REDUCE-IT™ Clinical Study Now Positioned to be Next Large Cardiovascular Outcomes Study to Report Results

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REDUCE-IT is the First Study of Any Therapy to Prospectively Enroll and Evaluate Risk Reduction for Cardiovascular Events in Statin-Treated Patients with Elevated Triglyceride Levels and Other Cardiovascular Risk Factors

REDUCE-IT Study Remains On-Track for Report of Top-Line Results Before the End of September 2018

BEDMINSTER, N.J., and DUBLIN, Ireland, Aug. 26, 2018 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health, today commented that following this week's European Society of Cardiology (ESC) Congress in Munich, Germany, Amarin's landmark cardiovascular outcomes study, REDUCE-IT™, is now likely to be the next large cardiovascular outcomes study to report results. As previously guided, top-line results from the REDUCE-IT study are expected to be reported before the end of September 2018. REDUCE-IT is evaluating the effect of Vascepa® (icosapent ethyl), administered at four (4) grams per day, as an add-on to statin therapy, on major adverse cardiovascular events (MACE) as compared to statin treated patients plus placebo. REDUCE-IT is the first cardiovascular outcomes study to be conducted in patients who despite low density lipoprotein cholesterol (LDL-C) control have risk factors for cardiovascular disease, including elevated triglyceride levels.

Deaths from cardiovascular disease are increasingly creating a worsening public health burden along with considerable pain, suffering and lost productivity. In the United States, heart disease is responsible for more than 800,000 deaths per year which is more deaths than from all types of cancer combined. Treatment of cardiovascular disease, including costs of treating heart attacks and strokes, is the highest area of healthcare treatment spending and projected to exceed USD 1 trillion within twenty years if not abated.[1] It is estimated that approximately one-fourth (57 million) of US adults, including nearly a third of those on statin therapy, have triglyceride (TG) levels that remain elevated (≥150 mg/dL).[2] Epidemiology studies show that this group has significant residual cardiovascular risk not addressed by standard of care statin therapy or other LDL ("bad") cholesterol-lowering therapies[3]. Despite being effective in lowering cardiovascular risk by 25%-35%, very significant levels of residual cardiovascular risk (65%-75%) remain for patients on statin therapy even after achievement of target LDL-C levels, often defined as <70 mg/dl.[3]

Amarin's REDUCE-IT study of Vascepa is noticeably different than the recently completed ASCEND trial presented today at ESC 2018. ASCEND studied a different drug in a different patient population. Some differences between the omega-3 arms of the ASCEND trial and the REDUCE-IT trial are noted in the table below:

	REDUCE-IT[4]	**ASCEND (OMEGA-3 ARMS)[5]**
RESULTS	Pending	Failed to achieve primary endpoints
SPONSOR/FUNDING	Amarin	Oxford Univ./British Heart Foundation
STUDY TYPE	Randomized, double-blind, placebo-controlled	Randomized, double-blind, placebo-controlled
PATIENT POPULATION	Statin-treated patients with high CV risk, including TG 150-499 mg/dL	Patients with diabetes, without evidence of cardiovascular disease
STUDIED OMEGA-3 TREATMENTS	Vascepa 4g/day (pure EPA)	Omacor® (Lovaza®) 1g/day (mixture of EPA, DHA and other)
STATIN THERAPY	Statin use mandated for all patients	Statin use not mandated
RESULT CAPTURE	Clinically run and monitored with periodic visits to clinical sites	Self-reported (results documented with questionnaires filled out by the patients every 6 months)
NUMBER OF PATIENTS	8,175	15,480
NUMBER OF PRIMARY EVENTS	~1,612 (expected)	1,401 (actual)
PRIMARY ENDPOINT	Risk Reduction for CV events (composite endpoint)	Risk Reduction for CV events (composite endpoint) & cancer

As reported today at ESC, the omega-3 arms of the ASCEND trial did not demonstrate a reduction of first serious vascular events with the therapy of omega-3 fatty acid supplementation studied[5]. Such finding is consistent with most prior studies of omega-3 mixtures.[3] The failure of the ASCEND study to demonstrate cardiovascular benefit serves as a reminder of the challenges to lowering cardiovascular risk.

Amarin reiterated its thesis that to lower cardiovascular risk beyond standard of care cholesterol management through statin therapy, important considerations include:

i. **Drug** being studied: Vascepa has been shown to lower levels of triglycerides and other potential atherogenic and inflammatory markers in studied patients without raising LDL-("bad") cholesterol. DHA containing omega-3 products and fenofibrates, in their approved labels report increases in LDL-cholesterol and other differences.
ii. **Dose** of drug must be adequate to have effect: Daily dose of 4g/day of Vascepa has been shown to have a significantly more pronounced impact on lipid levels than lower dose levels while maintaining a favorable safety profile.
iii. **Population** studied is important: Clinical benefit is best measured in patients who without treatment have a relatively high likelihood of experiencing a major adverse vascular event. The REDUCE-IT population is at a higher risk and is anticipated to show a higher event rate than reported in the ASCEND trial.

Amarin's thesis is being studied in the REDUCE-IT cardiovascular outcomes study. Amarin believes that REDUCE-IT is a study using the "right" drug, at the "right" dose in the "right" patient population.

Amarin looks forward to learning and reporting the top-line results of the REDUCE-IT study before the end of September 2018. Amarin remains blinded to the results of the REDUCE-IT study.

Vascepa capsules have been prescribed more than four (4) million times since 2013[6], and are affordably priced and covered by insurance for most patients.

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. Vascepa® (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. For more information about Amarin visit www.amarincorp.com.

About VASCEPA® (icosapent ethyl) Capsules

Vascepa® (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, known in scientific literature as AMR101, has been designated a new chemical entity by the FDA. 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 (≥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.
- In patients with hepatic impairment, monitor ALT and AST levels periodically during therapy.
- 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.
- Adverse events and product complaints may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.
- Patients receiving treatment with Vascepa and other drugs affecting coagulation (e.g., anti-platelet agents) should be monitored periodically.
- Patients should be advised to swallow Vascepa capsules whole; not to break open, crush, dissolve, or chew Vascepa.

FULL VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT 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 (≥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.

About Cardiovascular Disease

Worldwide, cardiovascular disease (CVD) remains the #1 killer of men and women. In the United States CVD leads to one in every three deaths – one death approximately every 38 seconds – with annual treatment cost in excess of $500 billion.[1, 7]

Beyond the cardiovascular risk associated with LDL-C, genetic, epidemiologic, clinical and real-world data suggest that patients with elevated triglycerides (TG) (fats in the blood), and TG-rich lipoproteins, are at increased risk for cardiovascular disease. [8, 9, 10, 11]

Leading clinical investigations seeking to address cardiovascular risk reduction beyond lowering LDL-C focus on interrupting the atherosclerotic process (e.g., plaque formation and instability) by beneficially affecting other lipid, lipoprotein and inflammation biomarkers and cellular functions thought to be related to atherosclerosis and cardiovascular events.

Forward-Looking Statements

This press release contains forward-looking statements, including expectations for timing of completion of the REDUCE-IT study, the potential for the results of the REDUCE-IT study to be positive and expectation for timing of announcements related to REDUCE-IT results. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. In particular, as disclosed in its previous company filings with the U.S. Securities and Exchange Commission, completing and reporting results from cardiovascular outcomes trials such as REDUCE-IT are complex undertakings that involve substantial risks such as the complex nature of collecting and analyzing clinical data and reliance on third parties. Vascepa may not show clinically meaningful effects in REDUCE-IT or support regulatory approvals for intended uses. In addition, Amarin's ability to effectively 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 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 the sale of pharmaceutical products, 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 not be upheld 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 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 (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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