June 12, 2017

Vascepa® (Icosapent Ethyl) Showed Reductions in Potentially Atherogenic Lipid Parameters in Statin-Treated Women With Type 2 Diabetes and Persistent High Triglycerides

BEDMINSTER, N.J. and DUBLIN, Ireland, June 12, 2017 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health, announced two EPA-related data presentations unveiled this week at the American Diabetes Association® 77th Scientific Sessions in San Diego, CA.

- A post-hoc analysis of the ANCHOR study further characterizing the efficacy and safety of prescription pure EPA Vascepa® (icosapent ethyl) in the subgroup of statin-treated women with persistent high triglycerides and diabetes mellitus type 2, showed that, compared with placebo, Vascepa reduced triglyceride levels and several other potentially atherogenic lipid parameters and inflammatory markers, and significantly increased blood EPA levels. The study titled, "Icosapent Ethyl in Statin-Treated Women with Persistent High Triglycerides and Diabetes Mellitus: ANCHOR Study Subanalysis," was led by Eliot A. Brinton, MD, FAHA, FNLA.

- An *in vitro* mechanistic study suggesting that EPA may be a potential strategy for reducing blood vessel cell dysfunction is summarized in a published presentation, "Eicosapentaenoic Acid Reduces Small Dense Low-Density Lipoprotein Oxidation and Human Endothelial Dysfunction in Vitro in a Manner Distinct from Docosahexaenoic Acid," by R. Preston Mason, PhD. The data demonstrated that EPA has antioxidant properties, distinct from DHA, that preserves certain cellular functions within blood vessel cells under disease-like conditions.

"Amarin continues to invest in research into the management of lipid disorders and patients at high risk of cardiovascular disease," expressed Eliot A. Brinton, MD. "The post-hoc analysis of ANCHOR study data explores the potential benefits and side effects of a therapy for women with diabetes that could help improve patient care." Amarin's ANCHOR trial was a 12-week trial that studied the effects of Vascepa in adult patients at high risk for cardiovascular disease with persistent high triglyceride levels (≥200 mg/dL and < 500 mg/dL) after stable statin therapy.

The ANCHOR study analysis was conducted in light of the correlation between elevated triglycerides and diabetes in women. The Centers for Disease Prevention and Control has indicated that without major changes in our diet and lifestyle, as many as 1 in 3 US adults could have diabetes by 2050. Analysis of study data on women with diabetes is particularly important, since women have often been underrepresented in clinical trials of patients with diabetes.

As is typical with subgroup analyses, limitations of the ANCHOR data analysis include the relatively small sample size (n=146), the 12-week study length and the post-hoc study design. Nonetheless, the results show potentially valuable changes in triglyceride levels and other lipoprotein parameters and inflammatory markers with Vascepa compared with placebo. The efficacy and safety of Vascepa 4 g/day in women were consistent with the overall ANCHOR study results. Limitations of the mechanistic study data include the simplistic and hypothesis-generating nature of *in vitro* data.

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 (200-499 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 recently announced that the REDUCE-IT study reached the onset of approximately 80% of the target aggregate number of primary cardiovascular events and that preparations are underway for an associated pre-specified interim efficacy analysis by the independent Data Monitoring Committee of REDUCE-IT. This analysis is expected to occur before the end of Q3 2017. Amarin expects that the trial will run to completion and that the onset of the target final primary cardiovascular event will likely be reached near the end of 2017.

Additional information on clinical studies of Vascepa can be found at 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® (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 is known in scientific literature as AMR101.

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.
- 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.

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. VASCEPA is under various stages of development for potential use in other indications that have not been approved by the FDA. 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 forward-looking statements, including statements about the potential efficacy and therapeutic benefits of Vascepa and EPA, including implications about the potential clinical importance of the findings presented as well as statements concerning the REDUCE-IT cardiovascular outcomes study. 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 uncertainties associated generally with retrospective subset analyses, research on biomarkers thought to be relevant in the treatment of cardiovascular disease, research and development and clinical trial risk generally, including the risk that study results in small sample sizes may not be predictive of future results in larger studies and that studied parameters may not have clinically meaningful effect. 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 we communicate with our investors and the public using our company website (www.amarincorp.com), our 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 we post on these channels and websites could be deemed to be material information. As a result, we encourage investors, the media, and others interested in Amarin to review the information that we post on these

channels, including our investor relations website, on a regular basis. This list of channels may be updated from time to time on our investor relations website and may include social media channels. The contents of our website or these channels, or any other website that may be accessed from our website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

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Source: Amarin Corporation plc