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Vascepa® (Icosapent Ethyl) Showed Reductions in Potentially Atherogenic Lipids and Inflammatory Markers in Patients With Persistent High Triglycerides and Elevated High-Sensitivity C-Reactive Protein (hsCRP)

BEDMINSTER, N.J. and DUBLIN, Ireland, March 12, 2018 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular (CV) health, presented an analysis showing that, consistent with overall study results from the ANCHOR trial, in statin-treated patients with persistent high triglycerides (TG) (200-499 mg/dL) and elevated hsCRP ≥2.0 mg/L, prescription pure EPA Vascepa 4 g/day significantly reduced TGs, other potentially atherogenic lipids and inflammatory parameters without increasing LDL cholesterol (LDL-C) vs. placebo. The poster was presented at the American College of Cardiology 67th Annual Scientific Session and Expo in Orlando, Florida.

The poster, "Icosapent Ethyl (Eicosapentaenoic Acid Ethyl Ester) Reduces Potentially Atherogenic Lipid, Lipoprotein, Apolipoprotein, and Inflammatory Parameters in High-Risk, Statin-Treated Patients With Persistent Elevated Triglycerides and High-Sensitivity C-reactive Protein: A Post hoc Subanalysis of the ANCHOR Study," reported that in statin-treated patients with TGs 200-499 mg/dL and hsCRP ≥2.0 mg/L, icosapent ethyl 4 g/day significantly reduced TGs and other potentially atherogenic and inflammatory parameters without increasing LDL-C vs. placebo. There was an 18%, statistically significant reduction of hsCRP as compared to placebo in this 12-week ANCHOR post-hoc analysis (p=0.02). Safety results were comparable to placebo, also consistent with overall ANCHOR study results.

The limitations of this analysis in statin-treated patients with hsCRP ≥2.0 mg/L and high TG at baseline include the modest sample size (n=126 and n=120, in the icosapent ethyl and placebo groups, respectively) and the post hoc nature of the analysis. hsCRP is a high-sensitivity quantification of C-reactive protein, an acute-phase protein released into the blood by the liver during inflammation, which has been associated with the presence of heart disease. As hsCRP is an acute-phase reactant and has high intra-individual variability, a single test for hsCRP, as was performed at each timepoint of the ANCHOR trial, may not accurately reflect an individual patient's basal or on-treatment hsCRP levels. Repeat measurement may be required to firmly establish an individual's basal hsCRP concentration, as well as to accurately understand treatment-induced changes in hsCRP. Moderate hsCRP levels (1-10 mg/L) have been associated with cardiovascular disease.

The ANCHOR study was not designed to determine effects on hsCRP or CV events. The ANCHOR trial was a multi-center, placebo-controlled, randomized, double-blind, 12-week pivotal Phase 3 study in patients with high TGs (≥200 mg/dL and < 500 mg/dL) who were also on statin therapy. 702 patients were enrolled in this trial. The primary endpoint in the trial was the percentage change in TG levels from baseline of Vascepa-treated subjects compared to placebo after 12 weeks of treatment. In April 2011, Amarin reported top-line results from the ANCHOR trial. The ANCHOR trial met its primary and secondary endpoints.

The clinical relevance of these data has not been determined. Amarin's REDUCE-IT trial is evaluating the potential benefit of icosapent ethyl on CV outcomes in statin-treated patients with high CV risk, including some patients with hsCRP ≥2.0 mg/L.

"We are excited to show the impact of Vascepa on these lipid and inflammatory biomarkers in patients with elevated hsCRP levels," expressed Michael Miller, MD. "The clinical community is looking forward to seeing the upcoming read-out of the REDUCE-IT trial."

The authors of this study were Michael Miller, MD, Department of Medicine, University of Maryland School of Medicine, Baltimore, MD; Christie M. Ballantyne, MD, Department of Medicine, Baylor College of Medicine and the Houston Methodist DeBakey Heart and Vascular Center, Houston, TX; Harold E. Bays, MD, Louisville Metabolic and Atherosclerosis Research Center, Louisville, KY; Craig Granowitz, MD, PhD, Ralph T Doyle, Rebecca A. Juliano, PhD, & Sephy Philip, RPh, PharmD, Amarin Pharma, Inc., Bedminster, NJ.

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 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 (150-499 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. As reported previously, Amarin expects to announce top-line results of this important study before the end of Q3 2018. The REDUCE-IT trial is being conducted under a Special Protocol Assessment agreement with the U.S. Food and Drug Administration.

Additional information on clinical studies of Vascepa can be found at www.clinicaltrials.gov.

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.
- 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. 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, including statements about the unknown clinical relevance of the findings presented as well as statements concerning the REDUCE-IT cardiovascular outcomes study such as the anticipated inclusion of certain patient populations, related timing and announcements with respect to final outcomes and the anticipated successful completion of the REDUCE-IT 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 modest sample sizes may not be predictive of future results in larger studies, that studied

parameters may not have clinically meaningful effect and the risk that patents may not adequately protect Vascepa against competition. 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 Annual Report on Form 10-K. 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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