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Vascepa® (Icosapent Ethyl) Showed Reductions in Potentially Atherogenic Lipid and Inflammatory Markers in Statin Treated Patients With Persistent High Triglycerides and Chronic Kidney Disease

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 health, announced an oral presentation titled, "Icosapent Ethyl Reduces Potentially Atherogenic Lipid and Inflammatory Markers in High-Risk Statin-Treated Patients With Stage 3 Chronic Kidney Disease and Persistent High Triglycerides." This oral presentation was held at the American Heart Association (AHA) 2017 Scientific Sessions in Anaheim, California.

Patients with stage 3 chronic kidney disease (CKD) and persistent high triglycerides (TG) despite statin therapy have a high risk of cardiovascular disease (CVD). The presentation of additional data from the phase 3 ANCHOR study of Vascepa® (icosapent ethyl) showed, in a post hoc analysis, that consistent with overall study results, Vascepa® 4 g/day (n=18) reduced potentially atherogenic lipid and inflammatory markers without raising LDL-C, and with a safety profile similar to placebo (n=35) in patients with CKD. These hypothesis-generating data warrant further prospective study to determine the clinical benefit of Vascepa, if any, as an adjunct to statin therapy in patients with CKD. The ongoing CVD outcomes trial with prescription, high-dose (4 grams/day) of icosapent ethyl in addition to statin therapy, REDUCE-IT, while not designed specifically to evaluate CVD outcomes in CKD patients, is expected to include some patients with CKD.

The authors of this presentation were Krishnaswami Vijayaraghavan (Kris Vijay), Scottsdale Cardiovascular Center, Scottsdale, AZ; Harold M. Szerlip, Baylor University Medical Center Dallas, TX; Christie M Ballantyne, Baylor College of Medicine and the Houston Methodist DeBakey Heart and Vascular Center, Houston, TX; Harold E. Bays, Louisville Metabolic and Atherosclerosis Research Center Louisville, KY; Sephy Philip, Ralph T. Doyle Jr, Rebecca A. Juliano, Craig Granowitz, Amarin Pharma, Inc., Bedminster, NJ.

"Amarin continues to delve into the potential dangers of cardiovascular disease," articulated Kris Vijay, MD. "We estimate that over 30 million people or fifteen percent of US adults have CKD[1], therefore, much more research is needed in this area. We look forward to the REDUCE-IT results to provide further data in patients with CKD."

As is typical with subgroup analyses, a limitation of this ANCHOR dataset analysis includes the post-hoc sub-analysis and relatively small sample sizes. Nonetheless, the results show potentially important changes in triglyceride levels and other potentially atherogenic lipid and inflammatory markers with Vascepa compared with placebo. The efficacy and safety of Vascepa 4 g/day in patients with Stage 3 CKD and persistent high triglycerides were consistent with the overall ANCHOR study results.

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 previously reported, Amarin expects that the onset of the target final primary cardiovascular event will be reached in Q1 2018, with results announced in Q2 or Q3 2018.

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. 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 and EPA, including implications about the potential clinical importance 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 the onset of the target final primary cardiovascular event and 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 small 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 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), 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.

References

[1] https://www.cdc.gov/diabetes/pubs/pdf/kidney_factsheet.pdf

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