Pure EPA Vascepa® (icosapent ethyl) Showed Reductions in Potentially Atherogenic Lipid and Inflammatory Parameters in Statin-Treated Women with Persistent High Triglycerides

November 14, 2016

BEDMINSTER, N.J. and DUBLIN, Ireland, Nov. 14, 2016 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) today announced an oral presentation at the American Heart Association Scientific Sessions 2016, New Orleans on November 14, 2016 that further characterized the efficacy and safety of Vascepa® (icosapent ethyl) in statin-treated women with persistent high triglyceride levels.

The presentation of additional data from the ANCHOR study showed, consistent with overall study results, that prescription pure EPA Vascepa® (icosapent ethyl) reduced triglyceride levels and several other potentially atherogenic lipid parameters and inflammatory markers in a subgroup of statin-treated women with persistent high triglycerides. The post hoc analysis supporting the efficacy of pure, prescription icosapent ethyl in this patient population was presented as an oral abstract (#309) titled, "Icosapent Ethyl (Eicosapentaenoic Acid Ethyl Ester) in Statin-Treated Women With Persistent High Triglycerides: Results From the ANCHOR Study."

The analysis is published in the *American Journal of Cardiology*; an early version of the manuscript is accessible at http://www.ajconline.org/article/S0002-9149(16)31738-6/pdf.

The analysis was led by Lori Mosca, MD, MPH, PhD, Professor of Medicine Emerita and Center Director of the American Heart Association Go Red for Women Research Network at Columbia University Medical Center, New York. Researchers observed that compared to placebo, Vascepa administered at 4 g/day significantly reduced triglycerides (TGs) without increasing LDL ("bad") cholesterol in women from the ANCHOR study with TG levels between 200 to 499 mg/dL. In addition, statistically significant improvements were observed in numerous potentially atherogenic parameters (lipids and lipoproteins) and inflammatory markers.

"It is important to generate data that address the specific needs of women, especially in fields where the data could prove useful to patient care," said Dr. Mosca. "While further study is needed and ongoing, this analysis is encouraging because the efficacy and safety of Vascepa 4 g/day in this subgroup of 91 statin-treated women with persistent high triglycerides were consistent with the overall ANCHOR results, which included 702 patients. It is vitally important to evaluate both potential benefits and side effects of therapies in women and not assume results from men are similar in women."

The clinical implications of lowering triglycerides with Vascepa 4 g/day are being investigated in the REDUCE-IT cardiovascular outcomes study of statin-treated women and men with persistent elevated TG levels.

The ANCHOR study and post hoc analysis were sponsored by Amarin and were not affiliated with or funded by the American Heart Association (AHA) or the AHA Go Red for Women Research Network.

About the Presented Research

Dr. Mosca's analysis was based on a post hoc subgroup analysis of 179 women in the ANCHOR trial, a study that investigated Vascepa as a treatment for patients with residual high TG (≥200 and &#60 500mg/dL) despite statin-induced control of LDL-C. ANCHOR enrolled 702 patients, of which the majority (73%) had Type 2 diabetes. The primary endpoint was percent change in TG levels from baseline to 12 weeks compared with placebo in subjects treated with placebo or Vascepa at 2 or 4 g/day. In April 2011, Amarin reported top-line results from the ANCHOR trial, which met its primary and secondary endpoints.

The subgroup analysis presented at the American Heart Association Scientific Sessions 2016 evaluated the efficacy of Vascepa on TG levels, potentially atherogenic (lipid and lipoprotein) parameters and inflammatory markers among a subgroup of women (97% white, 82% with diabetes, mean age 62 years) that were randomized to receive either Vascepa 4 g/day (n=91) or placebo (n=88) from baseline to week 12.

The analysis showed that, compared to placebo, Vascepa significantly reduced TGs (−22%; P &#60 0.0001) without increasing LDL-C (-6%; P &#62 0.05). Significant improvement in other potentially atherogenic parameters (non-HDL-C, VLDL-C, VLDL-TG, apoB, RLP-C) and inflammatory markers (Ox-LDL, Lp-PLA2, hsCRP) were also observed vs. placebo (P &#60 0.05 for all).

As with many subgroup analyses, a limitation is the small sample size, but the results are nonetheless suggestive of complementary beneficial changes in TG levels and other potentially atherogenic parameters and inflammatory markers as compared with placebo. The efficacy and safety of Vascepa 4 g/day in women were consistent with the overall ANCHOR results.

Amarin's clinical development program for Vascepa includes a trial known as REDUCE-IT. REDUCE-IT is a global Phase 3,

randomized, multicenter, double-blind, placebo-controlled study designed to evaluate whether treatment with Vascepa reduces cardiovascular events in patients who despite stabilized statin therapy have elevated triglyceride levels and other cardiovascular risk factors. The primary endpoint of the study is the time to the first occurrence of the composite endpoint of cardiovascular death, nonfatal myocardial infarction (heart attack), nonfatal stroke, coronary revascularization, or hospitalization for unstable angina. Secondary endpoints include time to event analyses of components of the primary endpoint. The study is being conducted under a special protocol assessment agreement with the FDA.

Additional information on ANCHOR, REDUCE-IT and Amarin's other 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 either 1 gram or 0.5 grams 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 &#62 2% and greater than placebo) was arthralgia (2.3% for Vascepa, 1.0% for placebo). There was no reported adverse reaction &#62 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 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.

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 the ongoing REDUCE-IT cardiovascular outcomes study. Vascepa® (icosapent ethyl), Amarin's first FDA-approved product, is a highly-pure, EPA-only, 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.

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 sub-set 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://www.amarincorp.com/investor-splash.html), 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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