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

BEDMINSTER, NJ and DUBLIN, IRELAND -- (Marketwired) -- 06/11/16 -- Amarin Corporation plc (NASDAQ: AMRN) today announced additional data on Vascepa (icosapent ethyl) presented at the annual meeting of the American Diabetes Association (ADA) supporting its efficacy in reducing concentrations of potentially atherogenic lipoproteins (lipoproteins that could promote fat deposits in arteries) in patients with Type 2 diabetes and persistent high triglyceride (TG) levels despite statin therapy.

The poster (#1173), titled "Effects of Icosapent Ethyl on Lipoprotein Particle Concentration and Size in Statin-Treated Patients with Persistent High Triglycerides: ANCHOR Patients with Diabetes Mellitus," was presented on June 11, 2016. Lipoproteins such as low density lipoprotein (LDL) and very low density lipoprotein (VLDL) carry cholesterol, fat, and other lipids in the blood and are considered potentially atherogenic at persistently elevated levels. Researchers using nuclear magnetic resonance (NMR) spectroscopy observed that, compared with placebo, Vascepa administered at 4 g/day significantly reduced the median concentrations of VLDL and LDL particles in patients with Type 2 diabetes who, despite statin therapy, have persistent high TG levels (≥ 200 and < 500 mg/dL).

The analysis was led by Eliot A. Brinton, MD, FAHA, FNLA; Director of Atherometabolic Research at the Utah Foundation for Biomedical Research, and President of the Utah Lipid Center, both in Salt Lake City. Dr. Brinton will be available at an author question and answer session on Sunday, June 12 from noon to 2:00 PM CDT.

"The findings presented today suggest multiple lipoprotein-related benefits of pure EPA Vascepa in patients with Type 2 diabetes, which merit further investigation of the potential cardiovascular benefits from icosapent ethyl therapy in cardiovascular outcomes trials," said Dr. Brinton. "In addition to the significant reductions in potentially atherogenic lipoprotein particle concentrations with Vascepa 4 g/day, apolipoprotein B (Apo B), which is carried on VLDL and LDL, was also significantly reduced by 9.3% compared with placebo. Furthermore, ApoB levels were correlated with levels of potentially atherogenic lipoproteins. While further study of Vascepa is needed and ongoing, ApoB and potentially atherogenic lipoprotein levels have been linked in the broader scientific literature to atherosclerosis and heart disease, so these new analyses support the hypothesis that Vascepa could prove beneficial to this historically difficult-to-treat patient population believed to be at increased cardiovascular risk."

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

About the Presented Research

Dr. Brinton's analysis was a post-hoc subgroup analysis of patients with Type 2 diabetes enrolled in the ANCHOR trial for whom NMR data were available. ANCHOR investigated Vascepa as a treatment for patients with residual high TG (≥ 200 and < 500 mg/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 data presented at ADA is an analysis of NMR measurements providing the concentration and size of lipoprotein particles (VLDL, LDL and HDL) in ANCHOR subjects with Type 2 diabetes, and comparing the results of subjects taking 4 g/day Vascepa (n=160) to those taking placebo (n=154).

The analysis showed that, compared with placebo, Vascepa significantly reduced the median concentration of: total (-11.3% ; $P=0.004$), large (-48.9% ; $P < 0.0001$), and medium (-12.0% ; $P=0.02$) VLDL particles; total (-7.4% ; $P=0.009$) and small (-13.1% ; $P < 0.0001$) LDL particles; and total (-7.5% ; $P < 0.0001$) and large (-29.7% ; $P < 0.0001$) HDL particles. In addition, potentially atherogenic particle concentration (defined as total VLDL + IDL + LDL) decreased significantly (-7.7% ; $P=0.003$). Both LDL and potentially atherogenic particle concentrations were significantly correlated with plasma Apo B at baseline ($R^2=0.49$; $P < 0.0001$ and $R^2=0.53$; $P < 0.0001$, respectively), which increased numerically for both at 12 weeks ($R^2=0.56$ $P < 0.0001$ and $R^2=0.64$ $P < 0.0001$, respectively).

The efficacy and safety of Vascepa 4 g/day in patients with Type 2 diabetes were consistent with the overall ANCHOR results.

As with many subgroup analyses, limitations of this analysis include the smaller sample size, the 12-week study duration and the post-hoc nature. Nonetheless, the results are suggestive of complementary beneficial changes in TG levels and lipoprotein parameters with Vascepa compared with placebo.

Amarin's clinical development program for Vascepa includes a trial known as REDUCE-IT, the first multinational cardiovascular outcomes study evaluating the benefit of 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 and < 500 mg/dL). Amarin recently announced that it has achieved its target enrollment of 8,000 patients for the trial and that an interim efficacy analysis by the independent Data Monitoring Committee of the REDUCE-IT trial is expected in September or October 2016.

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 1 gram 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.

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. 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 in short-term studies may not be predictive of future results in larger, longer-term 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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