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First Amendment Decision a Win for Amarin and Physician Plaintiffs

Federal Court Rules Promotion of ANCHOR Clinical Data of Vascepa(R) and Research on the Potential Connection Between Vascepa and Cardiovascular Risk Reduction Is Constitutionally Protected Speech

BEDMINSTER, NJ and DUBLIN, IRELAND -- (Marketwired) -- 08/07/15 -- Amarin Corporation plc (NASDAQ: AMRN) today announced a United States District Court has ruled that Amarin may promote to healthcare professionals certain uses of Amarin's lead product, Vascepa®(icosapent ethyl) capsules, that are not covered by current FDA-approved labeling for the drug so long as the promotion is truthful and non-misleading. The Court declaration covers promotion of the FDA-reviewed and agreed effects of Vascepa demonstrated in the ANCHOR clinical trial of patients with persistently high triglycerides after statin therapy and use of peer-reviewed scientific publications that present the current state of scientific research related to the potential of Vascepa to reduce the risk of cardiovascular disease. Based on today's ruling Amarin plans to begin promotional activities consistent with the opinion as soon as possible.

Decision is a victory aimed at improved patient care

The decision opens more direct and effective paths to communicate truthful and non-misleading information about Vascepa clinical trial results and the state of science relevant to the potential of Vascepa to reduce the risk of cardiovascular disease. With accurate information readily available, healthcare professionals will be better able to assess for themselves how best to choose among available treatment options for their patients. With healthcare professionals better informed, this decision is a victory that Amarin believes will lead to improved patient care.

Cardiovascular disease is the leading cause of death for men and women in the United States. Significant risk from cardiovascular disease remains for tens of millions of Americans after statin therapy and recommended changes in diet and exercise. Given the significant need to reduce the risk of cardiovascular disease, numerous independent national and international treatment guidelines and position statements recommend drug therapy as an adjunct to healthy diet, lifestyle change and statin therapy for at-risk patients with persistently high triglyceride levels in their blood to lower those patients' triglycerides and/or non-high-density lipoprotein cholesterol. The use of Vascepa in this patient population, as studied in the ANCHOR trial, is contemplated by guidelines, is medically accepted and commonly prescribed by physicians. This is the practical reality despite the fact that FDA did not approve Vascepa for this use and even though a link between such treatment and reduced cardiovascular risk has not been determined. Use of Vascepa within these guidelines is also listed on independent drug compendia on which reimbursement from Medicare, Medicaid and private payor plans is based. Amarin's REDUCE-IT cardiovascular outcomes study of Vascepa, which is designed to evaluate the efficacy of Vascepa in reducing cardiovascular mortality and morbidity in a high-risk patient population on statin therapy, is over 95% enrolled.

"This lawsuit is based on the principle that better informed physicians will make better treatment decisions for their patients," said John F. Thero, President and Chief Executive Officer. "Many physicians are aware of the efficacy data included in FDA-approved labeling for Vascepa but are not aware of efficacy data from the ANCHOR study of Vascepa. FDA has already included the safety data from both the MARINE and ANCHOR studies in approved Vascepa labeling. Amarin will now be able to communicate efficacy data from ANCHOR and other relevant study results to these physicians and to others in the medical community in the context of appropriate disclaimers."

The truthful and non-misleading information about Vascepa protected by the Court order

The Court determined that Amarin may engage in truthful and non-misleading speech promoting the off-label use of Vascepa, i.e., to treat patients with persistently high triglycerides, and specifically make to healthcare professionals the following truthful and non-misleading statements:

- Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. Vascepa should not be taken in place of a healthy diet and lifestyle or statin therapy.
- Vascepa is not FDA-approved for the treatment of statin-treated patients with mixed dyslipidemia and high (≥ 200 mg/dL and < 500 mg/dL) triglyceride levels due to current uncertainty regarding the benefit, if any, of drug-induced changes in lipid/lipoprotein parameters beyond statin-lowered low-density lipoprotein cholesterol on cardiovascular risk among statin-treated patients with residually high triglycerides. No prospective study has been conducted to test and support what, if any, benefit exists.
- Recent cardiovascular outcomes trials (ACCORD-Lipid, AIM-HIGH, and HPS2-THRIVE), while not designed to test the effect of lowering triglyceride levels in patients with high triglyceride levels after statin therapy, each failed to demonstrate

incremental cardiovascular benefit of adding a second lipid-altering drug (fenofibrate or formulations of niacin), despite raising high-density lipoprotein cholesterol and reducing triglyceride levels, among statin-treated patients with well-controlled low-density lipoprotein cholesterol.
- The ANCHOR trial demonstrates that Vascepa lowers triglyceride levels in patients with high (≥ 200 mg/dL and < 500 mg/dL) triglyceride levels not controlled by diet and statin therapy.
- In the ANCHOR trial, Vascepa 4g/day significantly reduced TG [triglycerides], non- HDL-C [non-high-density lipoprotein cholesterol or non-"good cholesterol,"] Apo B [Apolipoprotein B], VLDL-C [very-low-density lipoprotein cholesterol], TC [total cholesterol] and HDL-C [high-density lipoprotein cholesterol or "good cholesterol"] levels from baseline relative to placebo in patients with high (≥ 200 mg/dL and < 500 mg/dL) triglyceride levels not controlled by diet and statin therapy. The reduction in TG [triglycerides] observed with Vascepa was not associated with elevations in LDL-C [low-density lipoprotein cholesterol or "bad cholesterol] relative to placebo.

The Court's ruling also permits communication to healthcare professionals of the following information:

- peer-reviewed scientific publications relevant to the potential effect of EPA on the reduction of the risk of coronary heart disease, such as the JELIS cardiovascular outcomes trial of a pure-EPA product in Japanese patients and other publications on omega-3 acid studies; and
- more complete efficacy data from the ANCHOR trial.

To ensure that this speech is non-misleading, Amarin would also disclose the following:

- FDA has not approved to Vascepa reduce the risk of coronary heart disease;
- The effect of Vascepa on the risk of cardiovascular mortality and morbidity has not been determined;
- A cardiovascular outcomes study of Vascepa designed to evaluate the efficacy of Vascepa in reducing cardiovascular mortality and morbidity in a high-risk patient population on statin therapy is currently underway;
- Vascepa may not be eligible for reimbursement under government healthcare programs, such as Medicare or Medicaid, for treatment of statin-treated patients with mixed dyslipidemia and high (≥ 200 mg/dL and < 500 mg/dL) triglyceride levels or to reduce the risk of coronary heart disease. We encourage you to check that for yourself; and
- Any potential financial or affiliation biases between the firm and those who conducted the ANCHOR study.

About prohibitions on communication of off-label drug information

Once a drug is approved by FDA for a specific use in a specific patient population, physicians may exercise their medical judgment to prescribe the drug for any use in any patient population. It is estimated that approximately 20% of all prescriptions in the United States are used by physicians for such "off-label" indications. FDA has taken the position, however, that federal law prohibits pharmaceutical companies from proactively promoting data to the medical community regarding off-label uses -- even when such information is accurate, not misleading and reflective of accepted medical treatment.

FDA has acknowledged the importance of the off-label use of many pharmaceutical products. Federal, state and private health plans routinely pay for many off-label drug uses, including certain off-label uses of Vascepa. FDA permits limited communications on off-label uses, such as in response to unsolicited requests for information, under FDA's publication reprint guidance and in connection with scientific exchanges. Prior to this judgment, these restrictions significantly limited the flow of information about the specified off-label uses of Vascepa.

About the ruling and potential future proceedings

The ruling today by the Honorable Judge Paul Engelmayer of the United States District Court for the Southern District of New York granted Amarin and the physician plaintiffs relief in the form of a declaratory judgment. The ruling declared as unconstitutional, in this case with the specified disclosures, FDA off-label promotion restrictions.

An appeal of the Court's ruling can be filed within 60 days. The ruling will remain in effect until the Court makes a final decision in the case unless the ruling is appealed and overturned. The underlying litigation may proceed until the Court enters a final order in the case. The lawsuit did not seek and the ruling did not grant approval of the indication contemplated by the ANCHOR study.

About the REDUCE-IT cardiovascular outcomes study

The REDUCE-IT cardiovascular outcomes study is the first prospective double-blinded cardiovascular outcomes study of any drug in a population of patients who, despite stable statin therapy, have elevated triglyceride levels. The REDUCE-IT study is also the first cardiovascular outcomes study to test a high, 4-gram dose of a pure-EPA only omega-3 prescription product. In the REDUCE-IT study, pure-EPA Vascepa is being studied as an adjunct to, and not as a replacement for, statin therapy. If successful, Amarin plans to seek additional indicated uses for Vascepa that extend beyond the populations studied in the successful MARINE and ANCHOR trials of Vascepa. These additional indications would potentially address tens of millions of

patients in the United States and worldwide with elevated triglyceride levels despite stable statin therapy.

Amarin is blinded to the results of the REDUCE-IT study. The pooled, blinded event rate in the REDUCE-IT study is tracking to expectations for the study to continue until 2017 with results anticipated to be published in 2018. An interim review by the independent data monitoring committee of the efficacy and safety results of the trial is expected to occur during 2016 upon reaching 60% of the target aggregate number of cardiovascular events.

About VASCEPA ® (icosapent ethyl) capsules

VASCEPA® (icosapent ethyl) capsules, known in scientific literature as AMR101, is a highly pure-EPA omega-3 prescription product in a 1 gram capsule.

FDA-approved Indications 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 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 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 interpretations of the Court ruling and statements about the merits of legal arguments, whether the REDUCE-IT trial will continue as contemplated, whether the demonstrated clinical effects of Vascepa will result in cardiovascular risk reduction benefit in the REDUCE-IT trial and whether the results described herein will result in improved patient care. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. There can be no guarantee that Amarin will continue to be successful in this lawsuit. The litigation process could involve appeals and take a significant amount of time to reach final conclusion. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: the risk that Amarin's interpretation of the legal opinion and applicable legal standards may not be determinative or adjudicated definitively in Amarin's favor; the risk that the stated preliminary relief will not be permitted on a permanent basis and uncertainties associated generally with litigation, research and development, clinical trials and related regulatory approvals. There can be no assurance that promotion of the information allowed by the Court ruling will have a material impact on Amarin's operating results. While Amarin plans to increase certain sales and marketing costs to promote the newly allowed information to

healthcare professionals, the extent to which revenues may change as a result of such promotion cannot at this time be predicted. 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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