Amarin Corporation

Amarin Reports Last Patient Study Visit Has Occurred, an Important Step Towards Completion of REDUCE-IT™ Cardiovascular Outcomes Study

June 28, 2018

Study Remains On-Track for Q3 2018 Top-Line Results

BEDMINSTER, N.J., and DUBLIN, Ireland, June 28, 2018 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health, today announced that the last patient study visit has occurred in its potential landmark cardiovascular outcomes study, REDUCE-IT™. The company also reiterated that it anticipates having top-line results for this important study reported before the end of Q3 2018.

REDUCE-IT Status Update

In March 2018, patients commenced their last study visits as participants in the REDUCE-IT study. Completion of last patient visits is an important step towards finalizing the REDUCE-IT study and announcing results. As previously described, other important steps needed to complete the study include finalizing adjudication of reported events, including major adverse cardiovascular events (MACE) within the primary endpoint, securing final vital status data from inactive patients, and completing the review of data for consistency and completeness across more than 35,000 patient years in the trial.

The company reported that adjudication of all identified potential endpoints is approaching completion. As part of their last site visits in the study, patients underwent non-invasive diagnostic testing to determine whether silent myocardial infarctions or other clinical events had occurred. Until this testing was completed at the last patient visits, some cardiovascular events could not be finally adjudicated, even if these potential study endpoints occurred much earlier in the trial.

As is typical of large, multi-national, long-term outcomes studies, the final steps preceding REDUCE-IT completion include resolving remaining queries to contribute to a robust and accurate database. This “cleaning” process is characteristically intensive and time consuming. Progress is being made at a pace consistent with the company’s guidance of having top-line results to report before the end of Q3 2018.

Amarin continues to be intentionally blinded to the results of the study and will remain blinded to such results until after the study is completed and the database is locked.

Communication of REDUCE-IT Progress and Results

The series of steps being followed to complete the REDUCE-IT study is intended to support a robust understanding and reporting of results from this potentially landmark study. Amarin is highly motivated to announce the REDUCE-IT top-line results as soon as is practical. In parallel, the company is continuing its preparations for commercial expansion on the assumption of positive study results.

Once the REDUCE-IT database is locked, consistent with other outcomes studies, the company and a team of experts plan to confidentially review and analyze the data and promptly announce top-line results publicly. Broader reporting of results is targeted for a scientific conference in Q4 2018. The time between the database lock and reporting top-line results is intended to be as brief as is possible to support both timely and accurate reporting of the results. Consistent with the practices of most other companies, it is unlikely that Amarin will separately announce the date the database is locked. Rather, the company will focus on reporting the top-line results promptly after top-line results are known following database lock.

The time between commencing last patient study visits and reporting top-line results in other large outcomes studies reviewed by the company has been approximately five to seven months. There is no reliable correlation between the length of time needed to wind down a study (i.e., the time interval between commencement of patient last site visits and reporting top-line results) and the outcome of reported results of a study. Amarin’s anticipation of reporting top-line results before the end of Q3 2018 is consistent with the wind-down timing of these other outcomes studies, each of which were conducted by companies much larger than Amarin.

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 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.

About Cardiovascular Disease

Worldwide, cardiovascular disease (CVD) remains the #1 killer of men and women. In the United States CVD leads to one in every three deaths – one death approximately every 38 seconds – with annual treatment cost in excess of $500 billion.[1, 2]

Beyond the cardiovascular risk associated with LDL-C, genetic, epidemiologic, clinical and real-world data suggest that patients with elevated triglycerides (TG) (fats in the blood), and TG-rich lipoproteins, are at increased risk for cardiovascular disease. [3, 4, 5, 6]

Leading clinical investigations seeking to address cardiovascular risk reduction beyond lowering LDL-C focus on interrupting the atherosclerotic process (e.g., plaque formation and instability) by beneficially affecting other lipid, lipoprotein and inflammation biomarkers and cellular functions thought to be related to atherosclerosis and cardiovascular events.

Forward-Looking Statements

This press release contains forward-looking statements, including expectations for timing of completion of the REDUCE-IT study and the individual steps leading to completion as well as expectations on the company's ability to complete these steps in a manner that results in a robust and accurate database for the REDUCE-IT study; expectation for timing of announcements related to REDUCE-IT results and expectations regarding expanded promotion of Vascepa. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. In particular, as disclosed in its previous company filings with the U.S. Securities and Exchange Commission, completing and reporting results from cardiovascular outcomes trials such as REDUCE-IT are complex undertakings that involve substantial risks such as the complex nature of collecting and analyzing clinical data and reliance on third parties. Vascepa may not show clinically meaningful effects in REDUCE-IT or support regulatory approvals for intended uses. In addition, Amarin's ability to effectively commercialize Vascepa will depend in part on its ability to continue to effectively finance its business, efforts of third parties, its ability to create market demand for Vascepa through education, marketing and sales activities, to achieve market acceptance of Vascepa, to receive adequate levels of reimbursement from third-party payers, to develop and maintain a consistent source of commercial supply at a competitive price, to comply with legal and regulatory requirements in connection with the sale and promotion of Vascepa and to maintain patent protection for Vascepa. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: uncertainties associated generally with the sale of pharmaceutical products, research and development, clinical trials and related regulatory approvals; the risk that sales may not meet expectations and related cost may increase beyond expectations; the risk that patents may not be upheld in patent litigation and applications may not result in issued patents sufficient to protect the Vascepa franchise. 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 (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.

References

[1]American Heart Association. 2018. Disease and Stroke Statistics-2018 Update.

[2]American Heart Association. 2017. Cardiovascular disease: A costly burden for America projections through 2035.

[3] Budoff M. Triglycerides and triglyceride-rich lipoproteins in the causal pathway of cardiovascular disease. *Am J Cardiol*. 2016;118:138-145.

[4] Toth PP, Granowitz C, Hull M, et al. High triglycerides increase cardiovascular events, medical costs, and resource utilization in a real-world analysis of statin-treated patients with high cardiovascular risk and well-controlled low-density lipoprotein cholesterol [abstract]. *Circulation*. 2017;136(suppl 1):A15187.

[5] Nordestgaard BG. Triglyceride-rich lipoproteins and atherosclerotic cardiovascular disease - New insights from epidemiology, genetics, and biology. *Circ Res*. 2016;118:547-563.

[6] Nordestgaard BG, Varbo A. Triglycerides and cardiovascular disease. *Lancet.* 2014; 384: 626–635.

Amarin Contact Information

Investor Relations:
Elisabeth Schwartz
Investor Relations and Corporate Communications
Amarin Corporation plc
In U.S.: +1 (908) 719-1315
investor.relations@amarincorp.com

Lee M. Stern
Trout Group
In U.S.: +1 (646) 378-2992
lstern@troutgroup.com

Media Inquiries:
Kristie Kuhl
Finn Partners
In U.S.: +1 (212) 583-2791
Kristie.kuhl@finnpartners.com

Primary Logo

Source: Amarin Corporation plc