August 4, 2016

Amarin and FDA Reaffirm Concurrence on REDUCE-IT Through Special Protocol Assessment Agreement Amendment

Primary Endpoint and Overall Study Timing and Size Unchanged; Statistical Analysis Plan Finalized; Second Interim Efficacy Analysis and Additional Pre-Specified Endpoints Added

BEDMINSTER, NJ and DUBLIN, IRELAND -- (Marketwired) -- 08/04/16 -- Amarin Corporation plc (NASDAQ: AMRN) today announced that the U.S. Food and Drug Administration (FDA) agreed to an amendment of the company's special protocol assessment (SPA) agreement for the REDUCE-IT cardiovascular outcomes study reaffirming concurrence on critical components of the revised study protocol and analysis plans and incorporating recommendations from the trial's independent oversight committees.

Key new elements reflected in the company's amendment include:

- Finalized details of the statistical analysis plan covering both final and interim efficacy analyses;
- Added a second pre-specified interim efficacy analysis at approximately 80% of the 1,612 primary cardiovascular events targeted for completion of the study; and
- Expanded to over 30 the number of pre-specified secondary and tertiary endpoints in an effort to more fully capture the broad potential clinical effects of Vascepa® (icosapent ethyl) and the diversity of the patient population being studied.

The amendment does not change the primary endpoint or the overall size of the REDUCE-IT study or the company's prior guidance on timing. Prospective study of additional endpoints could lead to improved patient care for specific groups within the diverse population studied in REDUCE-IT. The addition of a second interim efficacy analysis at approximately 80% completion is expected to facilitate the compilation of the final locked dataset at study end and potentially shorten the time needed to complete final analysis and final result reporting.

"This amendment reflects timely modification and fine tuning of an already robust clinical trial design and helps ensure that expectations are clear between all parties directly involved regarding the formalities of data presentation and analysis at trial completion and interim looks," commented Steven Ketchum, Ph.D., chief scientific officer of Amarin. "Residual cardiovascular risk is high in the patient population being studied in REDUCE-IT. Because of this important unmet clinical need, the opportunity it presents and the years invested in this study, our goal is to promptly report and broadly publish the multiple findings anticipated from the study. We remain confident that REDUCE-IT is positioned for success."

Statistical Analysis Plan Finalized

The primary endpoint of REDUCE-IT is the time from randomization to the first occurrence of a composite of adjudicated cardiovascular events (including cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, coronary revascularization, or hospitalization for unstable angina). Consistent with the protocol, patients in REDUCE-IT have been randomized in a 1:1 ratio to either the Vascepa plus statin treatment arm of the study or to the placebo plus statin treatment arm of the study. The time to the first occurrence of the composite endpoint will be compared between arms.

REDUCE-IT is designed to provide 90% power to detect a 15% relative risk reduction between arms. The final analysis for the comparison of the time to onset of the first primary cardiovascular event between the treatment and control groups will be considered significant if the two-sided p-value is less than 0.0422.

The planned interim analyses by the DMC are based on a group sequential design with classic O'Brien-Fleming boundaries generated using the typical Lan-DeMets alpha-spending function. The use of the spending function allows for possible deviations from the target event numbers at the times of the respective interim analyses. As is standard with similar statistical assessments and permitted by study protocol, should either the first or second planned interim efficacy analysis include slightly more or slightly fewer adjudicated events, the target p-value stopping boundaries will be adjusted accordingly. The statistical analysis plan for REDUCE-IT does not include futility analysis at either interim analysis.

Amarin will remain blinded to the interim and ongoing results of the REDUCE-IT study as well as to any interim p-values or other statistical information until after the study is stopped and the database is locked, either at the final analysis or, in the

event of a determination by the independent DMC of overwhelming efficacy, at an interim analysis. Guidelines for the independent DMC to recommend stopping the study at an interim analysis for overwhelming efficacy require that the study achieve the applicable pre-specified statistical significance threshold for the primary endpoint for that interim analysis, and generate robust efficacy evidence on selected subgroup analyses for the primary endpoint and certain pre-specified secondary outcome measures, to support an overall favorable benefit/risk profile. Given the high thresholds of overwhelming efficacy required prior to a DMC recommending an early stop to a cardiovascular outcomes trial like REDUCE-IT, Amarin continues to expect that the DMC's 60% and 80% interim analyses will each result in a recommendation to continue the REDUCE-IT study as planned.

First Efficacy Analysis Anticipated Within 90 Days

As previously announced, late in the first quarter of 2016, the onset of approximately 60% of the target aggregate number of primary cardiovascular events triggered formal preparation for a protocol-specified interim efficacy and safety analysis by the DMC. The study has undergone multiple prior safety reviews by the DMC with each such review resulting in a DMC recommendation that REDUCE-IT continue as planned. The upcoming interim analysis in the September-October timeframe will include the first review of unblinded efficacy data by the DMC.

To be considered statistically significant at this interim look, based on the assumption that exactly 60% of target events are adjudicated and available for assessment by the DMC, the primary efficacy analysis must show that the two-sided p-value for relative risk reduction on the primary endpoint is less than 0.0076 in favor of the Vascepa plus statin treatment arm.

Second Efficacy Analysis Added

Preparations for the second planned interim efficacy analysis will be triggered by the onset of approximately 80% of the target aggregate number of primary cardiovascular events in the study. Based on historical event rates, Amarin anticipates that the onset of approximately 80% of events will occur in the first half of 2017, with the second pre-specified interim efficacy and safety analysis by the DMC expected around mid-2017.

Assuming that exactly 80% of the target primary events have been adjudicated and included in the second interim efficacy analysis by the DMC, the primary efficacy analysis must show that the two-sided p-value for relative risk reduction on the primary endpoint is less than 0.0220 in favor of the Vascepa plus statin treatment arm.

Final Efficacy Analysis Anticipated in 2018

The final analysis will be conducted from a locked database after notification that 1,612 primary cardiovascular events have been formally adjudicated. Amarin currently expects that the final event will occur in the second half of 2017, with top-line data announcement anticipated in 2018.

If the study is continued until the planned end, subsequent to the two interim efficacy analyses by the DMC, the final analysis for the comparison of the time to onset of first primary cardiovascular event between the treatment and control groups will be considered significant if the two-sided p-value is less than 0.0422. This final p-value reflects accepted statistical methodology for adjustment of multiple analyses.

Secondary and Tertiary Endpoints Expanded

Recognizing the potential to observe broad beneficial impact from treatment with Vascepa in REDUCE-IT, the study's statistical analysis plan now includes more than 30 pre-specified secondary and tertiary endpoints designed to capture multiple potential drug effects in multiple additional sub-populations. Such pre-specified endpoints are designed to better assess the potential therapeutic benefits of Vascepa across multiple patient subpopulations and support a variety of related new publications. We anticipate these publications could help us improve patient care by supporting informed medical decisions in the treatment of cardiovascular disease.

"The data generated by this trial, if successful, could define how residual cardiovascular risk is treated in the studied patient population," added Dr. Ketchum. "As a result, the comprehensive value of REDUCE-IT data could come not just from a statistically significant reduction in risk for the overall patient population, which is paramount, but also from the potential for consistent and robust REDUCE-IT data across multiple secondary outcome measures and patient subgroups. We seek efficacy and safety results that are unequivocal, robust, and consistent to provide the strongest foundation from which to seek expanded labeling for Vascepa."

About Special Protocol Assessment Agreements

An SPA agreement documents FDA's agreement that the design and planned analysis of a study can adequately address

objectives in support of a regulatory submission. The FDA agreed that, based on the information submitted to the agency, the critical elements of the revised REDUCE-IT protocol and analysis plans would support a regulatory submission based on the study's primary endpoint. Secondary and/or tertiary endpoints, their clinical significance, or whether any such endpoints would yield results appropriate for labeling are considered review issues and are not intended to be a binding component of the REDUCE-IT SPA agreement. An SPA agreement is not a guarantee of approval. An SPA agreement is generally binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining safety or efficacy is identified after the study begins, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA. The FDA reserves the right of final determinations for approval based on its review of the entire data presented in a marketing application.

About 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 have persistently elevated triglyceride levels despite stabilized statin therapy. The primary endpoint of the study is the time to the first occurrence of the composite endpoint of cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, coronary revascularization, or hospitalization for unstable angina. Secondary endpoints include time to event analyses of components of the primary endpoint.

Additional information on the REDUCE-IT trial 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, including implications about the potential clinical importance of the potential findings from REDUCE-IT; statements regarding the REDUCE-IT study's potential success and its effects on patient care, including as relating to the more than 30 pre-specified secondary and tertiary endpoints focused on additional effects and patient sub-populations; the expected timing of the planned 60% and 80% interim data analyses by the DMC and related effects on the analysis and reporting of final data from the REDUCE-IT study; expectations regarding the DMC's recommendations to continue the REDUCE-IT study as planned following the 60% and 80% interim data analyses; expectations regarding the timing of the final cardiovascular event in the REDUCE-IT study and the release of top-line data; and the potential for an expansion of the approved Vascepa label based on the possible results 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 research on biomarkers thought to be relevant in the treatment of cardiovascular disease, as well as research and development and clinical trial risk generally, including the risk that study results may not be predictive of future results 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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Source: Amarin Corp. Plc