

Amarin's AMR101 Phase 3 ANCHOR Trial Meets all Primary and Secondary Endpoints with Statistically Significant Reductions in Triglycerides at Both 4 Gram and 2 Gram Doses and Statistically Significant Decrease in LDL-C

- Triglyceride levels decreased 21.5% and 10.1% from baseline versus placebo at 4 gram and 2 gram doses, respectively
- LDL-C decreased at both doses within the predefined non-inferiority boundary with a statistically significant 6.2% decrease in LDL-C from baseline versus placebo at 4 gram dose
- All results were incremental to background statin therapy
- Safety profile similar to placebo and similar to MARINE trial results
- Results position AMR101 to be first-in-class product for treatment of high triglycerides Conference Call and Webcast Scheduled for Today at 8:00 a.m. EDT

MYSTIC, Conn. and DUBLIN, April 18, 2011 /PRNewswire/ -- Amarin Corporation plc (Nasdaq: AMRN), a clinical-stage biopharmaceutical company with a focus on cardiovascular disease, today reported positive, statistically significant top-line results from its ANCHOR trial for the Company's lead product candidate, AMR101. The Phase 3 trial met its primary and secondary efficacy endpoints for both the 4 gram and 2 gram daily doses.

The purpose of the ANCHOR trial was to demonstrate that AMR101 is effective in reducing triglyceride levels in patients with high triglycerides without increasing LDL-C ("bad cholesterol") levels in patients on background statin therapy. The ANCHOR trial investigated AMR101 as a treatment for high triglycerides (≥200 and <500mg/dL) in 702 patients with mixed dyslipidemia (two or more lipid disorders) on background statin therapy at LDL-C (low-density lipoprotein cholesterol) goal who were at high risk of cardiovascular disease. The majority of these patients were diabetic (73%). This is the largest trial with omega-3 therapy conducted in this important patient population. All patients were on background statin therapy with simvastatin, atorvastatin or rosuvastatin. Despite the benefits of statin therapy, patients in this population have significant residual risk for cardiovascular events. The trial's primary endpoint was defined as the percentage change in triglyceride levels from baseline compared to placebo after twelve weeks of treatment. In addition, the study was powered to demonstrate a lack of LDL-C elevating effect with AMR101 compared to placebo. The trial was conducted under a Special Protocol Assessment (SPA) agreement with the FDA.

Triglyceride Reduction Levels Exceeded Company Expectations

The primary endpoint for triglyceride change was achieved at both 4 grams and 2 grams per day with median placebo-adjusted reductions in triglyceride levels of 21.5% and 10.1% for the 4 grams and 2 grams per day dose groups, respectively. These reductions were both statistically significant (p<0.0001 and p = 0.0005, respectively). The median baseline triglyceride levels were 259 mg/dL, 265 mg/dL and 254 mg/dL for the patient groups treated with placebo, 4 grams and 2 grams of AMR101 per day, respectively. Even greater reductions in triglycerides were noted with higher potency statin regimens. Results were positive and statistically significant in both the diabetic and non-diabetic patient groups.

LDL-C Reductions Surpass Target of LDL-C Neutrality

The trial's key secondary endpoint was to demonstrate a lack of elevation of LDL-C in order to avoid offset to the primary target of cholesterol lowering therapy. The trial's non-inferiority criterion for LDL-C was met at both AMR101 doses. The upper confidence boundaries for both doses were below the pre-specified +6% LDL-C threshold limit. In fact, at the 4 gram dose the upper confidence boundary was below zero (-1.7%) and at the 2 gram dose the upper confidence boundary was close to zero (0.05%). Moreover, for the 4 grams per day AMR101 group, LDL-C decreased significantly by 6.2% from baseline versus placebo, demonstrating superiority over placebo (p=0.0067). For the 2 grams per day group, LDL-C decreased by 3.6% from baseline versus placebo (p=0.0867).

Additional Findings and Safety Profile were Positive

In addition, the ANCHOR trial demonstrated statistically significant decreases in all predefined secondary endpoints at both doses studied. These endpoints were non-HDL-C, Apo B (Apolipoprotein B), Lp-PLA2 (lipoprotein phospholipase A2) and VLDL-cholesterol. Non-HDL-C decreased in the 4 grams per day group by 13.6% (p<0.0001) and in the 2 grams per day group by 5.5% (p=0.0054) compared to placebo. These are important lipid biomarkers as they represent predictors of cardiovascular risk. Apo B is a sensitive index of residual cardiovascular risk and is generally considered to be a better predictor than LDL-C. Lp-PLA2 is an enzyme found in blood and atherosclerotic plaque; high levels have been implicated in the development and

progression of atherosclerosis. The safety profile of AMR101 was similar to placebo and there were no treatment-related serious adverse events in the trial. These results confirm and build upon the positive results for the MARINE Phase 3 trial announced in November 2010. The Company expects to present more details of these results at an upcoming scientific meeting.

Principal Investigator and Company Very Encouraged by Results

"The design and execution of the ANCHOR trial were robust and the trial results were very clearly positive," said Christie M. Ballantyne, M.D., Methodist DeBakey Heart and Vascular Center, Houston, and principal investigator of the ANCHOR trial. "I am very impressed with the performance of AMR101. In particular, whereas current triglyceride-lowering drugs may raise LDL-C and causes patient treatment concerns, AMR101 demonstrated a decrease in LDL-C beyond the decrease created by statin therapy. Furthermore, it is very encouraging for patient care that AMR101 caused reductions in significant markers of cardiovascular risk such as Apo B and non-HDL-C. The greater triglyceride reduction in patients with higher potency statin regimens is also very encouraging."

Commenting on the ANCHOR trial results, Joseph S. Zakrzewski, Chief Executive Officer and Executive Chairman of Amarin, stated, "We are delighted by the results of the ANCHOR trial. In November we announced MARINE trial results which position AMR101 to be best-in-class for treating patients with very high triglycerides. The ANCHOR trial results are even more remarkable than the broadly positive MARINE trial results. We believe these results clearly differentiate AMR101 from other triglyceride lowering therapies and position AMR101 to be both first-in-class and best overall therapy for treating the high triglyceride population. We thank the ANCHOR team, including our investigators, for their many contributions to this outstanding study design and execution."

Large Market Potential

In the U.S. alone, approximately 40 million people have triglyceride levels above 200 mg/dL. The majority of these patients have high triglyceride levels of ≥200 and <500mg/dL as studied in the ANCHOR trial with approximately 4 million of these people having very triglyceride levels ≥500 mg/dL as studied in the MARINE trial. Currently, no omega-3 based product is approved for the indication studied in the ANCHOR trial. In the seven largest pharmaceutical markets (U.S., Japan and five largest European markets), it is estimated that over 100 million people have mixed dyslipidemia.

Conference Call and Webcast Information

Amarin will host a conference call at 8:00 a.m. EDT today, April 18, 2011, to comment on the ANCHOR results and the Company's current operating and strategic objectives. To participate in the call, please dial (877) 407-0778 within the U.S. or (201) 689-8565 from outside the U.S. A replay of the call will be made available for a period of two weeks following the conference call. To hear a replay of the call dial (877) 660-6853 (inside the U.S.) or (201) 612-7415 (outside the U.S.). A replay of the call will also be available via the Company's Web site shortly after the call. For both dial-in numbers please use account number 286 and conference ID 371147. The conference call can also be heard live via the investor relations section of the Company's Web site at www.amarincorp.com.

About ANCHOR

The ANCHOR trial, a multi-center, placebo-controlled, randomized, double-blind, 12-week pivotal study to evaluate the efficacy and safety of 2 grams and 4 grams of AMR101, enrolled 702 patients with fasting triglyceride levels from 200 mg/dL to less than 500 mg/dL who were also on background statin therapy (treated to the National Cholesterol Education Program Adult Treatment Panel III (NCEP III) target goal of 100 mg/dL). Patients in this trial were characterized as having high triglyceride levels according to the NCEP III treatment guidelines. The secondary endpoints in the ANCHOR trial include the difference in LDL-cholesterol levels between AMR101-treated and placebo-treated groups to demonstrate that the addition of AMR101 to statin therapy does not increase LDL-cholesterol (LDL-C or "bad cholesterol") in this population. Both treatment groups received statin therapy for the treatment of high LDL-cholesterol. Secondary measures in the ANCHOR trial were the difference in other lipid and biomarker levels between AMR101 and placebo treatment groups.

The three background statins used in the ANCHOR trial, simvastatin, atorvastatin or rosuvastatin, represent approximately 80% of statins currently used. The most common trade names for these drugs are Zocor®, Lipitor® and Crestor®, respectively.

About AMR101

AMR101 is a prescription-grade omega-3 fatty acid, comprising not less than 96% ultra pure icosapent ethyl (ethyl-EPA), that Amarin is developing as a potentially best-in-class prescription medicine for the treatment of patients with very high triglyceride levels (>500 mg/dL) and as a potentially first-in-class therapy for patients with high triglyceride levels (≥200 and <500mg/dL) who are also on statin therapy for elevated LDL-cholesterol levels. Significant scientific and clinical evidence support the efficacy and safety of ethyl-EPA in reducing triglyceride levels.

About Amarin

Amarin Corporation plc is a clinical-stage biopharmaceutical company with expertise in lipid science focused on the treatment of cardiovascular disease. The Company's lead product candidate is AMR101 (icosapent ethyl). The Company reported positive, statistically significant top-line results for both of its two pivotal Phase 3 clinical trials, the MARINE trial (investigation of AMR101 as a treatment for patients with very high triglycerides [>500 mg/dL]), as reported on November 29, 2010 and the ANCHOR trial, as reported above. The Company is planning to file an NDA for AMR101 before the end of Q3, 2011. The Company is evaluating which data, in addition to safety data, from the ANCHOR trial to include in this NDA. If the ANCHOR results are added to the NDA, the NDA would seek approval for the indication studied in the MARINE trial with the ANCHOR results either as a separate indication for use or referenced in the label as data supporting the safe use of AMR101 in the treatment of high triglyceride levels in statin-treated patients who have mixed dyslipidemia. In order to obtain a separate indication for AMR101 based on the ANCHOR trial results, the FDA requires that we have a clinical outcomes study substantially underway at the time of the NDA filing. The Company is in the late stages of designing this outcomes study. The results of an outcomes study are not required for FDA approval of the broader indication and an outcomes study is not required for the indication being studied in the MARINE trial. The MARINE and ANCHOR trials were conducted under separate Special Protocol Assessment (SPA) agreements with the U.S. Food and Drug Administration (FDA). Amarin also has next-generation lipid candidates under evaluation for preclinical development.

Disclosure Notice

This press release contains forward-looking statements, including statements about the success of clinical trial results the timing of and content of regulatory filings, the likelihood of approval, the potential label of any approved drug, competitive market positioning and the commercial opportunity for AMR101, including the number of patients that could potentially benefit from AMR101, and the timing of data publication. These forward-looking statements are not promises or quarantees and involve substantial risks and uncertainties. Among the factors that could cause actual results to differ materially from those described or projected herein are the following: anticipated operating losses and the likely need for additional capital to fund future operations; uncertainties associated generally with research and development, clinical trials and related regulatory approvals; the risk that SPAs are not a guarantee that FDA will accept an NDA or approve a product candidate upon submission; uncertainties relating to the further analysis of the ANCHOR and MARINE trials; dependence on third-party manufacturers, suppliers and collaborators; significant competition; loss of key personnel; and uncertainties associated with market acceptance and adequacy of reimbursement, technological change and government regulation. A further list and description of these risks, uncertainties and other matters can be found in Amarin's filings with the U.S. Securities and Exchange Commission, including its most recent Annual Report on Form 10-K. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company 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.

Investor Contact Information:

Stephen D. Schultz Investor Relations and Corporate Communications Amarin Corporation In U.S.: +1 (860) 572-4979 x292 investor.relations@amarincorp.com

Lee M. Stern The Trout Group In U.S.: +1 (646) 378-2922 Istern@troutgroup.com

Media Contact Information:

David Schull or Martina Schwarzkopf, Ph.D.
Russo Partners
In U.S.: +1 (212) 845-4271 or +1 (212) 845-4292 (office) +1 (347) 591-8785 (mobile)
david.schull@russopartnersllc.com
martina.schwarzkopf@russopartnersllc.com

SOURCE Amarin Corporation plc

News Provided by Acquire Media