

# Additional Detail of Successful MARINE Phase III Trial to be Presented at the National Lipid Association 2011 Annual Scientific Sessions

## Data Presented for Secondary and Exploratory Endpoint of Pivotal Study of AMR101 Includes Statistically Significant Reductions Compared to Placebo for Important Lipid Biomarkers

NEW YORK, May 19, 2011 (GLOBE NEWSWIRE) -- Amarin Corporation plc (Nasdaq:AMRN), a clinical-stage biopharmaceutical company with a focus on cardiovascular disease, today summarized additional MARINE Phase 3 pivotal trial results being presented at the National Lipid Association 2011 Annual Scientific Sessions (NLA) in New York City. In November 2010, the Company announced top-line results from the MARINE trial, which studied AMR101 as a therapy for patients with very high triglyceride levels (>500 mg/dL). The NLA is an association of clinical lipidologists, lipid researchers and allied clinical team members comprising of a total of five regional chapters representing more than 3,500 members from across the United States.

The MARINE study was the largest study ever conducted with omega-3 fatty acids in treating patients with very high triglycerides (>500 mg/dL). AMR101 (icosapent ethyl) was studied in this population, compared to placebo, at doses of 4 grams and 2 grams per day. As reported in November 2010, the primary endpoint of the MARINE study was achieved with statistically significant reductions in triglycerides compared to placebo of 33% (P<0.0001) for the 4 gram and 20% (P=0.0051) for the 2 gram doses, respectively. AMR101 did not result in an increase in median LDL-C compared to placebo at either dose. The NLA-presented poster will provide additional data on secondary and exploratory efficacy endpoints, patient demographics and safety and tolerability of AMR101.

Regarding the secondary and exploratory efficacy endpoints, the Company believes these are important lipid biomarkers as they represent predictors of cardiovascular risk. Apo B (Apolipoprotein B) is a sensitive index of residual cardiovascular risk and is generally considered to be a better predictor than LDL-C. Lp-PLA2 (Lipoprotein-phospholipase A2), is an enzyme found in blood and atherosclerotic plaque; high levels have been implicated in the development and progression of atherosclerosis. AMR101 4 gram per day demonstrated significant reductions compared to the placebo groups in:

- Apo B by 8.5% (p = 0.0019)
- Lp-PLA2 by 13.6% (p = 0.0003)
- Non—HDL-C by 17.7% (p <0.0001)
- VLDL-cholesterol by 28.6% (p = 0.0023)

The 2 gram per day dose significantly reduced placebo-corrected median non—HDL-C by 8.1% (p = 0.0182). The 2 gram per day dose also significantly reduced placebo-corrected median VLDL-cholesterol by 15.3% (p < 0.05) while reductions in Apo B and Lp-PLA2 compared to placebo were not statistically significant. Both doses significantly reduced total cholesterol (TC) with no significant effect on HDL-C. In addition, AMR101 4 g/day demonstrated statistically significant reduction in high sensitivity C-reactive protein (hsCRP) (p = 0.0012); this is an important marker of vascular inflammation.

In statin-treated patients, AMR101 4 gram per day reduced placebo-corrected median triglyceride levels by 65% (p = 0.0001) and AMR101 2 gram per day reduced placebo-corrected median triglyceride levels by 40.7% (p = 0.0276). Among patients with baseline triglycerides >750 mg/dL, AMR101 4 gram per day reduced placebo-corrected median triglycerides in this subgroup by 32.9% (p = 0.0016).

In general, most patients were overweight (mean body mass index 30.8 kg/m<sup>2</sup>), white (88.2%), and male (76.4%), with a mean age of 53 years. Among randomized patients, 25% received background statin therapy, 27.5% had diabetes mellitus, and 55% were at high risk for cardiovascular disease. For the randomized population, the median triglyceride level was 679.5 mg/dL, with 39% of these patients having baseline triglycerides >750 mg/dL. The median baseline LDL-C level was 86.0 mg/dL in the intent-to-treat (ITT) population.

The incidence of treatment-emergent adverse events (TEAEs) was generally similar across the three treatment groups. Most TEAEs were mild to moderate in severity, not related to study drug (as assessed by blinded investigators), and the severity of TEAEs were comparable between treatment groups. The most common TEAEs (>3% in any treatment group) were gastrointestinal (diarrhea, nausea, and eructation), with the highest numerical incidences in the placebo group.

This is the first time these MARINE results will be presented at a medical and scientific forum. The MARINE study results will be presented by its principal investigator, Harold Bays, M.D., Medical Director of Louisville Metabolic and Atherosclerosis Research Center.

"We believe these data demonstrate pure EPA therapy effectively treats elevated triglycerides without raising LDL-C levels, as often occurs with other DHA containing omega-3 therapies," said Dr. Bays. "This trial was the largest study of a highly purified omega-3 fatty acid administered to patients with very high triglycerides. MARINE showed for the first time that pure EPA therapy reduces triglyceride levels, improves a broad array of lipid and non-lipid parameters, and all without a significant increase in LDL-C. As importantly, AMR101 was well tolerated, with adverse effects similar to placebo."

According to Joseph Zakrzewski, Executive Chairman and CEO of Amarin, "The MARINE results exceeded our expectations and position Amarin to be best-in-class for treating patients with very high triglycerides and we believe AMR101 will offer patients the option to reduce triglycerides without the side effects seen with current omega-3 and fibrate therapies. At the same time, the significant reductions seen in the new data on other lipid biomarkers would suggest that pure EPA can potentially provide broader cardiovascular benefit."

The Company added that further presentation of the MARINE trial results is scheduled for oral presentation at the European Society of Cardiology (ESC) Congress 2011 in August and for publication in *The American Journal of Cardiology* in September. In addition, Amarin also has a poster accepted for presentation at the ESC congress on novel data from the MARINE study; this will describe the effects of AMR101on the fatty acid profile in plasma and red blood cells in patients with very high triglycerides.

### About AMR101

AMR101 is a prescription-grade omega-3 fatty acid, comprising not less than 96% ultra pure EPA (icosapent ethyl), 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 (which we refer to as mixed dyslipidemia). Significant scientific and clinical evidence support the efficacy and safety of ethyl-EPA in reducing triglyceride levels and other important lipid and inflammation biomarkers, including Apo-B, non-HDL-C, Total-Cholesterol, VLDL-C, Lp-PLA2, and hs-CRP without increasing LDL-C. AMR101 demonstrated a safety profile comparable to placebo in both trials.

### **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 (investigation of AMR101 for the treatment of patients on statin therapy with high triglycerides [>200 and <500mg/dL] with mixed dyslipidemia), as reported on April 18, 2011. Both the MARINE and the ANCHOR trials were conducted under 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 efficacy, safety and benefits of the Company's product candidates, clinical trial results and the timing of data publication. 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 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; the risk that historical clinical trial enrolment and randomization rates may not be predictive of future results; uncertainties relating to the timing of data collection and analysis for 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 and 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. 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.

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