



## **Amarin Completes All Non-Clinical Work for AMR101 NDA Submission**

### **Company Progresses Toward Regulatory Submission This Quarter**

MYSTIC, Conn. and DUBLIN, July 7, 2011 (GLOBE NEWSWIRE) -- Amarin Corporation plc (Nasdaq:AMRN), a clinical-stage biopharmaceutical company with a focus on cardiovascular disease, announced today the successful completion of the remaining non-clinical studies for the Company's planned new drug application (NDA) for AMR101 for the treatment of patients with very high triglycerides ( $\geq 500$  mg/dL) and confirmed an expected Q3 2011 NDA submission.

Specifically, Amarin reported the successful completion of a 26-week carcinogenicity study to evaluate the oncogenic potential of AMR101 in transgenic mice, the second of two required rodent carcinogenicity studies. In addition the Company announced the successful completion of the final in-vitro studies supporting the non-clinical package for the NDA.

"Successful completion of these studies is important progress as they represent necessary studies to support our NDA submission," said Joseph Zakrzewski, Amarin's Chairman and CEO. "Completion of these NDA-enabling activities helps pave the way for the Company to submit an NDA for AMR101 before the end of September."

#### **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 ( $\geq 500$  mg/dL) and as a potentially first-in-class therapy for patients with high triglyceride levels ( $>200$  and  $<500$  mg/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 two complete Phase 3 clinical 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). Amarin 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  $<500$  mg/dL] with mixed dyslipidemia), as reported on April 18, 2011. Both the MARINE and 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 timing of NDA submission, the results of non-clinical studies and the efficacy, safety and benefits of AMR101. 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, non-clinical studies, 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 regarding regulatory approval generally and the requirements for approval; 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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