Amarin Announces Global Supply Network for AMR101

Company Adds Multiple Suppliers to Increase Capacity and Flexibility in Preparation for Commercial Launch of AMR101

MYSTIC, Conn. and DUBLIN, May 31, 2011 (GLOBE NEWSWIRE) -- Amarin Corporation plc (Nasdaq:AMRN), a clinical-stage biopharmaceutical company with a focus on cardiovascular disease, announced today the expansion of its capability to supply AMR101 through the addition of two active pharmaceutical ingredient (API) suppliers and two encapsulators.

Equateq Limited (Equateq) and Chemport Inc. (Chemport) have agreed to provide Amarin with API for AMR101. Catalent Pharma Solutions LLC (Catalent) and Banner Pharmacaps Europe B.V. (Banner) have agreed to terms with Amarin to provide soft-gel encapsulation services for AMR101. These agreements expand Amarin's entire supply chain and provide the Company with significantly greater global capacity and diversification in preparation for the commercial launch of AMR101.

Joseph Zakrzewski, Executive Chairman and CEO, stated, "A primary 2011 goal for Amarin is to expand our global supply chain to support expected product demand, diversify our supply base and ensure cost-efficient supply. The positive ANCHOR and MARINE clinical trial results heightened the timing and urgency of achieving that goal. We believe that the addition of these suppliers position us, subject to regulatory approval, for an aggressive launch of AMR101."

API Suppliers

Equateq, based in Scotland, and Chemport, based in South Korea, are companies with substantial expertise in manufacturing polyunsaturated fatty acids for use in both pharmaceutical and nutraceutical products. Prior to entering into agreements with these companies, Amarin conducted an extensive worldwide evaluation of companies with expertise in manufacturing fatty acid-based products. Based on this evaluation, the Company concluded that the majority of the potential suppliers lacked the technical skills and product quality infrastructure needed to consistently produce icosapent ethyl for AMR101 that is greater than 96% pure eicosapentaenoic acid (EPA). Amarin believes that Equateq and Chemport possess the technical competence, quality capabilities and regulatory experience needed to produce icosapent ethyl, the active ingredient in AMR101, to Amarin's high quality standards. Amarin also believes that Equateq and Chemport have the capabilities to scale-up and qualify their facilities to meet the requirements of Amarin and regulatory authorities.

It is the Company's current plan, subject to the submission of a New Drug Application (NDA) and approval, to launch AMR101 based on product produced by its existing API supplier. Amarin has created a protocol, with feedback from regulatory authorities, for the qualification of additional API suppliers. The Company's aim is for Equateq and Chemport to complete all necessary qualification steps needed to facilitate the submission of a supplemental NDA promptly upon any approval of the AMR101 NDA Amarin plans to submit in the third quarter of this year. This brings the total number of API suppliers in Amarin's current supply chain to three (3).

Encapsulation

Catalent Pharma Solutions, headquartered in Somerset, New Jersey, and Banner, headquartered in High Point, North Carolina, are both leading global providers of prescription softgel capsulation services. The Company selected these suppliers based on their technical abilities, quality standards and cost. The Company has used Banner for encapsulation services for many years, including encapsulation for all of the Company's AMR101 clinical trials.

Financial Considerations

Equateq and Chemport, as well as Amarin's current API supplier, are each executing phased capacity expansion plans aimed at creating sufficient capacity to meet anticipated demand for metric tons of API for AMR101 (each metric ton provides capacity for approximately a million 1-gram capsules of AMR101). These API suppliers are self-funding these expansion plans with limited contributions from Amarin as described below. Notwithstanding this API support plan, in light of the better than expected Phase 3 ANCHOR clinical trial results and significant anticipated sales volume, the Company is considering adding a fourth API supplier.

In connection with the Equateq agreement, subject to approval of the Equateq API, in return for certain exclusivity provisions, Amarin is obligated to make minimum annual purchases from Equateq ranging from approximately $10 to $20 million. In addition, Amarin has agreed pay Equateq a one-time commitment payment of $1.0, development fees up to a maximum of $0.5 million as well as up to $5.0 million payments for purchasing initial raw materials to be credited against future API purchases.

In connection with the Chemport agreement, subject to approval of the Chemport API, in return for certain exclusivity provisions, Amarin is obligated to make minimum annual purchases from Chemport ranging from approximately $7.5 to $15 million. Concurrent with its agreement with Chemport for commercial supply, Amarin agreed to make a minority share equity investment in Chemport of up to $3.3 million.

In conjunction with the Equateq and Chemport agreements, Amarin is responsible for the execution and cost of certain regulatory activities as well as certain minimum purchase requirements.

The Company anticipates that, subject to regulatory approval to market and sell AMR101, actual levels of API purchased will exceed the minimum levels specified above. The Company anticipates encapsulating the API it purchases; however, no lump-sum or minimum dollar amount payments are required in the terms with which the Company has agreed with Catalent and Banner.

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). 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 <500mg/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 efficacy, safety and benefits of the Company's product candidates, manufacturing capacity and qualification of AMR101 suppliers, the Company's anticipated payment obligations under these agreements, the timing and likelihood of regulatory approvals and commercial potential for 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, 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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