



## **Amarin Announces Submission of Supplemental New Drug Application for Novasep as Fourth Vascepa(R) Active Pharmaceutical Ingredient Supplier**

August 26, 2013

BEDMINSTER, N.J. and DUBLIN, Ireland, Aug. 26, 2013 (GLOBE NEWSWIRE) -- Amarin Corporation plc (Nasdaq:AMRN), a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health, announced today the submission of a Supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) seeking approval for Novasep Group, S.A.S., through its subsidiary Finorga S.A.S., as an additional Vascepa® (icosapent ethyl) active pharmaceutical ingredient (API) supplier. Novasep is part of the previously disclosed Slanmhor consortium with which Amarin announced a global supply agreement in 2012.

Novasep, a global leader in purification technologies and API manufacturing, is building the world's largest chromatography plant using its proprietary chromatography technologies to produce API on behalf of the Slanmhor consortium and Amarin. Amarin anticipates the Novasep facility, located in Mourenx, France, to be qualified and operational for manufacturing in 2014.

"This sNDA submission for Novasep brings to four the total number of suppliers that are approved or in regulatory review for Vascepa API production, including Nisshin Pharma, Inc. and following the recent FDA approvals of both BASF and Chemport as API suppliers for the product," stated Joseph Zakrzewski, Chairman and Chief Executive Officer of Amarin. "The Novasep submission represents an additional step toward the goal of expanding our global supply chain to support expected Vascepa demand, diversify our supply base and ensure cost-efficient supply. As previously stated, the continued addition of these suppliers will potentially lead to API cost reductions of up to 50% or more and help us reach a steady state gross margin as a percentage of product revenues in the high seventies to low eighties."

This submission contributes to the planned expansion of the Vascepa manufacturing supply chain and is additional progress toward Amarin's goal to protect the commercial potential of Vascepa to beyond 2030 through a combination of patent protection, regulatory exclusivity, trade secrets and by taking advantage of manufacturing barriers to entry. Along with this planned expansion in supply, Amarin's significant progress includes expansion of patent protection for Vascepa in the United States with 27 Amarin patents either issued or allowed and over 30 additional patent applications being prosecuted in the United States. Amarin is also making significant progress with its patent applications related to Vascepa in multiple jurisdictions outside the United States, including the May 2013 patent grant by the European Patent Office covering the use of Vascepa based on the results from the MARINE trial.

### **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. Vascepa® (icosapent ethyl), Amarin's first FDA approved product, is a patented, ultra pure omega-3 fatty acid product comprising not less than 96% EPA. For more information about Vascepa visit [www.vascepa.com](http://www.vascepa.com). For more information about Amarin visit [www.amarincorp.com](http://www.amarincorp.com).

### **About the Slanmhor consortium**

As previously disclosed, the Slanmhor consortium includes Slanmhor Pharmaceuticals, Inc., Royal DSM, and Novasep Group S.A.S., each respectively headquartered in Canada, Holland and France. Each of these companies has extensive experience in providing omega-3 API manufacturing solutions. Slanmhor, which heads the consortium, is a wholly-owned subsidiary of Clearwater Fine Foods, Inc., a Canadian based investment holding company with principal holdings that also include seafood harvesting, processing and telecommunications. Novasep employs 1,200 people and has numerous FDA inspected facilities and a global footprint that includes numerous API manufacturing plants, biopharmaceutical production sites and equipment manufacturing facilities. Its Mourenx, France, plant is intended to be the first manufacturing plant used by the Slanmhor consortium to manufacturing Vascepa API for Amarin.

### **Forward-looking statements**

This press release contains forward-looking statements, including statements about the manufacturing capacity and qualification of Vascepa suppliers, potential product cost reductions from future supply sources, potential future gross margins from the sale of Vascepa, the timing and likelihood of regulatory submissions and approvals, the timing of manufacturing readiness for supply and Amarin's ability to protect the commercial potential of Vascepa. 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 dependence on third parties, research and development, clinical trials and related regulatory submissions and approvals; cost containment efforts and factors contributing to

gross margins; events that could interfere with the issuance of a patent, or once issued, the continued validity or enforceability of a patent; Amarin's ability to maintain adequate patent protection and successfully enforce patent claims against third parties; commercializing Vascepa without violating the intellectual property rights of others; obtain regulatory exclusivity and take advantage of manufacturing barriers to entry. 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 Annual 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](http://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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