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# Amarin Announces FDA New Chemical Entity Market Exclusivity Determination for Vascepa(R) (icosapent ethyl) Capsules

BEDMINSTER, NJ and DUBLIN, IRELAND -- (Marketwired) -- 05/31/16 -- Amarin Corporation plc (NASDAQ: AMRN) announced today that the U.S. Food and Drug Administration (FDA) has determined that Vascepa® (icosapent ethyl) capsules are eligible for five-year, new chemical entity (NCE), marketing exclusivity pursuant to the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act. This determination provides Vascepa with the benefits of NCE exclusivity afforded by statute. NCE exclusivity for Vascepa runs from its date of FDA approval on July 26, 2012 and extends until July 26, 2017. The statutory 30-month stay triggered by patent litigation following generic application submissions permitted on July 26, 2016 would expire on January 26, 2020, seven-and-a-half years from FDA approval.

"Amarin's goal is to protect the commercial potential of Vascepa to 2030," stated John F. Thero, president and chief executive officer of Amarin. "NCE regulatory exclusivity complements multiple patents covering Vascepa with expiration dates in 2030."

***About VASCEPA ® (icosapent ethyl) capsules***

VASCEPA® (icosapent ethyl) capsules are a single-molecule prescription product consisting of 1 gram of the omega-3 acid commonly known as EPA in ethyl-ester form. Vascepa is not fish oil, but is derived from fish through a stringent and complex FDA-regulated manufacturing process designed to effectively eliminate impurities and isolate and protect the single molecule active ingredient. Vascepa is known in scientific literature as AMR101.

FDA-approved Indication and Usage

- VASCEPA (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe ( ≥ 500 mg/dL) hypertriglyceridemia.
- The effect of VASCEPA on the risk for pancreatitis and cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined.

Important Safety Information for VASCEPA

- VASCEPA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to VASCEPA or any of its components.
- Use with caution in patients with known hypersensitivity to fish and/or shellfish.
- The most common reported adverse reaction (incidence > 2% and greater than placebo) was arthralgia (2.3% for Vascepa, 1.0% for placebo). There was no reported adverse reaction > 3% and greater than placebo.
- Patients receiving treatment with VASCEPA and other drugs affecting coagulation (e.g., anti-platelet agents) should be monitored periodically.
- In patients with hepatic impairment, monitor ALT and AST levels periodically during therapy.
- Patients should be advised to swallow VASCEPA capsules whole; not to break open, crush, dissolve, or chew VASCEPA.
- Adverse events and product complaints may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.

FULL VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT WWW.VASCEPA.COM.

***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. Amarin's clinical program includes a commitment to the ongoing REDUCE-IT cardiovascular outcomes study. Vascepa® (icosapent ethyl), Amarin's first FDA-approved product, is a highly-pure, EPA-only, omega-3 fatty acid product available by prescription. For more information about Vascepa, visit www.vascepa.com. For more information about Amarin, visit www.amarincorp.com.

***Forward-looking statements***

This press release contains forward-looking statements, including statements about whether NCE exclusivity and Amarin patents would adequately protect Vascepa against competition and Amarin's plan 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 herein include the following: events that could interfere with the continued validity or enforceability of a patent; Amarin's ability generally to maintain adequate patent protection and successfully enforce patent claims against third parties; withstanding any challenge to FDA's NCE determination; commercializing Vascepa without violating the intellectual property rights of others; and uncertainties associated generally with research and development, clinical trials and related regulatory approvals and exclusivity grants. 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 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. 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), 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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