# Amarin and Eddingpharm Announce Agreement to Develop and Commercialize Vascepa(R) (icosapent ethyl) in China

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BEDMINSTER, NJ and DUBLIN, IRELAND, and MACAO S.A.R, PEOPLE'S REPUBLIC OF CHINA -- (Marketwired) -- 02/26/15 -- Amarin Corporation plc (NASDAQ: AMRN) and Eddingpharm, two pharmaceutical companies focused on the development and commercialization of innovative therapeutics, today announced an exclusive agreement for Eddingpharm to develop and commercialize Vascepa<sup>®</sup> (icosapent ethyl) in the territories of the Mainland China, the Hong Kong and Macao Special Administrative Regions and Taiwan for uses that are currently commercialized and under development by Amarin in the United States based on the MARINE, ANCHOR and ongoing REDUCE-IT clinical trials of Vascepa.

Under the agreement, Eddingpharm will be responsible for development and commercialization activities in the territory and associated expenses. Amarin will provide development assistance and be responsible for supplying finished, and later bulk, product. Terms of the agreement include up-front and milestone payments to Amarin of up to \$169.0 million, including a non-refundable \$15.0 million up-front payment and development, regulatory and sales-based milestone payments of up to an additional \$154.0 million. Eddingpharm will also pay Amarin tiered double-digit percentage royalties on net sales of Vascepa in the territory escalating to the high teens. Amarin will supply product to Eddingpharm under negotiated supply terms.

The Chinese pharmaceutical market has been growing at an annual rate of approximately 20% during the past ten years and currently is the third largest pharmaceutical market in the world. This trend is expected to continue and enable the territory to surpass Japan as the second largest pharmaceutical market in the world by the end of this decade. The combination of the high prevalence rates of hypertriglyceridemia and large population size suggest that a great number of patients in China would benefit from therapy with Vascepa. To date, there has been no prescription grade pharmaceutical omega-3 product in China, and thus there is a high unmet need for an efficacious and safe product to treat the millions of patients that have related lipid abnormalities.

Vascepa is indicated in the United States as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. Vascepa also demonstrated favorable effects on triglycerides and a spectrum of other lipid, lipoprotein and inflammatory biomarkers in the Phase 3 ANCHOR clinical trial of adult patients with high triglycerides (≥200 mg/dL and &#60 500 mg/dL) despite statin therapy. Vascepa is currently being studied in a multinational cardiovascular outcomes study, the REDUCE-IT study, to evaluate its effectiveness in reducing the prevalence of first major cardiovascular events in a high-risk patient population. REDUCE-IT enrollment of an estimated 8,000 patients is expected to be completed in 2015, with a protocol pre-specified interim data analysis of efficacy and safety results at 60% of targeted events anticipated in 2016 by the independent Data Monitoring Committee (DMC). Completion of the REDUCE-IT study, if not stopped earlier based on the interim analysis by the independent DMC, is expected in 2017 with published results expected to be available in 2018. Successful REDUCE-IT trial results would position Vascepa to be the first and only prescription grade omega-3 product approved for augmentation to statin therapy for cardiovascular risk reduction indications, a potentially multi-billion dollar commercial opportunity in the United States alone, and position Vascepa for a similar indication in China for which the opportunity is also large.

"Vascepa has the potential to occupy a leading position in the substantial worldwide market for prescription omega-3 products," commented John F. Thero, President and Chief Executive Officer of Amarin. "Our agreement with Eddingpharm reflects the culmination of a competitive process and represents a significant step toward commercializing Vascepa in a major market outside the United States. We are very pleased to be collaborating with Eddingpharm. We believe that their team is well suited to successfully introduce Vascepa in China. Eddingpharm has established development and regulatory capabilities and an impressive commercial organization that has launched many innovative products in China. Eddingpharm's successful track record of long-term alliances with leading global pharmaceutical companies gives us confidence in Vascepa's success in China. The agreement also validates the Vascepa and REDUCE-IT investment hypothesis and marks our start at licensing the ex-US rights to Vascepa to leading commercialization partners around the world."

"There is a large unmet need for a high-quality, well-studied and differentiated prescription grade omega-3 product in the Chinese market," commented Xin Ni, Founder, Chairman and Chief Executive Officer of Eddingpharm. "We are delighted that Amarin has entrusted Eddingpharm to develop and commercialize Vascepa in Greater China. Vascepa has significant commercial potential in the rapidly growing Chinese market. Together with Amarin, we are committed to bringing this medicine to millions of patients in the region."

## About Vascepa® (icosapent ethyl) capsules

Vascepa® (icosapent ethyl) capsules, known in scientific literature as AMR101, is a highly pure-EPA omega-3 prescription product in a 1 gram capsule.

### Indications and Usage

- Vascepa (icosapent ethyl) is indicated in the United States 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 and should be used with caution in patients with known hypersensitivity to fish and/or shellfish.

• The most common reported adverse reaction (incidence &#62 2% and greater than placebo) was arthralgia (2.3% for Vascepa, 1.0% for placebo). There was no reported adverse reaction &#62 3% and greater than placebo.

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

Vascepa has been approved for use by the United States Food and Drug Administration (FDA) as an adjunct to diet to reduce triglyceride levels in adult patients with severe (<u>&#62.500 mg/dL</u>) hypertriglyceridemia. Vascepa is under various stages of development for potential use in other indications that have not been approved by the FDA. Nothing in this press release should be construed as marketing the use of Vascepa in any indication that has not been approved by the FDA.

#### 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 commitment to an ongoing outcomes study. Vascepa<sup>®</sup> (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 <a href="https://www.vascepa.com">www.vascepa.com</a>. For more information about Amarin visit <a href="https://www.amarincorp.com">www.vascepa.com</a>.

#### About Eddingpharm

Eddingpharm, founded in 2001, is a leading and fast growing specialty pharmaceutical company in the Chinese market, committed to actively introducing quality products into China's pharmaceutical market. The company focuses on the development, distribution and promotion of pharmaceutical products in five therapeutic areas: cardiovascular, clinical nutrition, oncology, antibiotics and respiratory system. Eddingpharm has established long-term cooperative relationships with a number of multinational pharmaceutical companies and overseas specialty pharmaceutical companies, including GlaxoSmithKline, B. Braun, Chisei, Ablynx, Syndax, ALK and Cardiome. Eddingpharm has built a competitive product portfolio and pipeline in five major therapeutic areas. Eddingpharm established its U.S. affiliate and set up a product development team with R&D capabilities in Los Angeles, California, to coordinate and communicate with leading global R&D institutions and explore opportunities for introducing innovative pharmaceutical products in China. The company currently employs over 700 people.

#### Forward-looking statements

This press release contains forward-looking statements, including statements about the potential for successful development and commercialization of Vascepa in China; economic benefits and costs anticipated from the development and commercialization of Vascepa in China; the efficacy, safety and therapeutic benefits of Vascepa and the commercial success of the collaboration effort and agreement; the potential for favorable results from the REDUCE-IT clinical trial and the potential for regulatory approvals and commercial opportunities that may result therefrom. 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 the ability to effectively commercialize Vascepa will depend in part on the ability to clinically develop Vascepa in China successfully, obtain necessary regulatory approvals, create market demand for Vascepa through education, marketing and sales activities, achieve market acceptance of Vascepa, receive adequate levels of reimbursement from third-party payers, develop and maintain a consistent source of commercial supply at a competitive price, and maintain patent and exclusivity protection. Other factors include uncertainties associated with clinical trials, regulatory reviews, commercial success, new collaborations and the ability of commercial partners to work together effectively to achieve intended results. 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

## Availability of other information about Amarin

Investors and others should note that we communicate with our investors and the public using our company website (<a href="http://www.amarincorp.com">www.amarincorp.com</a>), our investor relations website (<a href="http://www.amarincorp.com/investor-splash.html">http://www.amarincorp.com/investor-splash.html</a>), 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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