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Amarin Announces Commencement of VASCEPA® Clinical Development in Mainland China

BEDMINSTER, N.J. and DUBLIN, Ireland, Jan. 17, 2018 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), a biopharmaceutical company focused on the commercialization and development of therapeutics, today announced that a clinical trial of Vascepa® (icosapent ethyl) capsules in a patient population with severe hypertriglyceridemia (TG ≥500 mg/dL) has been commenced in Mainland China, or China, by Amarin's partner, Eddingpharm. Under the parties' February 2015 agreement, Eddingpharm is responsible for Vascepa development, regulatory activities, commercialization and associated costs, including managing and funding this pivotal registration study.

Similar to the MARINE trial conducted by Amarin, the trial being conducted by Eddingpharm in China is a multi-center, placebo-controlled, randomized, double-blind, 12-week study that is enrolling patients with severe hypertriglyceridemia, more commonly known as very high triglycerides, or VHTG. The study's primary endpoint is the percentage change in triglyceride levels from baseline compared to placebo after 12 weeks of treatment. Eddingpharm anticipates that the study will be completed within the next two years. This clinical trial puts Vascepa on track to be the first ever pure prescription grade EPA based drug product in China. The parties believe the commercial opportunity in China is largely based on the prevalence of hypertriglyceridemia, which is estimated to affect around 17.7%[1] of the adult Chinese population, about 185 million people.[2]

In November 2010, Amarin reported top-line results for the MARINE trial which met its primary and other key efficacy endpoints. The MARINE trial demonstrated that Vascepa 4g/day significantly lowered triglycerides by 33% compared to placebo without increasing LDL-C (non-significant decrease of 2% vs. placebo). In addition, Vascepa demonstrated a statistically significant decrease compared to placebo in multiple other important lipid biomarkers in MARINE including non-high-density lipoprotein cholesterol (non-HDL-C), apolipoprotein B (apo B), lipoprotein-phospholipase A2 (Lp-PLA2), very low-density lipoprotein cholesterol (VLDL-C), total cholesterol (TC) and the inflammatory marker high-sensitivity C-reactive protein (hsCRP).

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 an ongoing outcomes study. Vascepa® (icosapent ethyl), Amarin's first FDA approved product, is a highly-pure, 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.

About Eddingpharm

Eddingpharm is a fast-growing Chinese specialty pharmaceutical company, committed to bringing to the Chinese healthcare market high-quality medicines from all over the world, providing patients with more treatment options and better healthcare opportunities. Eddingpharm promotes the communication and collaboration between Chinese clinical experts and leading international medical research institutes, and provides academic support to Chinese clinical doctors. Eddingpharm has a strong footprint in top tier cities - the core healthcare market in China - and is growing rapidly in lower tier cities. Eddingpharm's wide and expanding coverage includes more than 17,000 hospitals and 15,000 pharmacies in 30 provinces with a sales force of over 1,000 professional personnel. Eddingpharm has successfully expanded its product portfolio through in-licensing, joint ventures, strategic alliances, exclusive distribution, and other forms of collaboration with multinational pharmaceutical companies, specialty pharmaceutical companies, and biotech companies in the US and Europe. For more information, visit www.eddingpharm.com

About VASCEPA® (icosapent ethyl) capsules

Vascepa® (icosapent ethyl) capsules are a single-molecule prescription product consisting 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. Amarin has been issued multiple patents

internationally based on the unique clinical profile of Vascepa, including the drug's ability to lower triglyceride levels in relevant patient populations without raising LDL-cholesterol levels.

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.

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 (≥500 mg/dL) hypertriglyceridemia. Nothing in this press release should be construed as promoting the use of Vascepa in any indication that has not been approved by the FDA.

Forward-looking statements

This press release contains forward-looking statements, including statements about the potential for successful 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; and the potential and timing 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 a result of new information, future events or circumstances or otherwise.

Availability of other information about Amarin

Investors and others should note that Amarin communicates with its investors and the public using the company website (http://www.amarincorp.com/), the investor relations website (http://investor.amarincorp.com/), 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 Amarin posts on these channels and websites could be deemed to be material information. As a result, Amarin encourages investors, the media, and others interested in Amarin to review the information that is posted on these channels, including the investor relations website, on a regular basis. This list of channels may be updated from time to time on Amarin's investor relations website and may include social media channels. The contents of Amarin's website or these channels, or any other website that may be accessed from its website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

References:

1) Huang et al. Population Health Metrics 2014, 12:28
2) Derived from China National Bureau of Statistics, 2010, http://www.stats.gov.cn/tjsj/pcsj/rkpc/6rp/indexch.htm

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