Amarin Shares Topline Data from Partner's Pivotal Phase 3 Study of VASCEPA® (Icosapent Ethyl) in Mainland China

November 19, 2020

Significant Reduction in Triglyceride Levels Without Low-Density Lipoprotein Cholesterol (LDL-C) Increase Compared to Placebo and Safety Profile Similar to Placebo Achieved with 4 Grams Per Day Dose of Icosapent Ethyl in Chinese Patients with Very High Triglycerides (≥500 mg/dL)

Results Support Upcoming Submission by Partner, Edding, Seeking Regulatory Approval in China

DUBLIN, Ireland and BRIDGEWATER, N.J., Nov. 19, 2020 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) today shared positive, statistically significant top-line results from Protocol Number EDPC003R01, a Phase 3 clinical trial of VASCEPA® (icosapent ethyl) conducted in China by Amarin partner, Edding. The study, which investigated VASCEPA as a treatment for patients with very high triglycerides (≥500 mg/dL), met its primary efficacy endpoint as defined in the clinical trial protocol and demonstrated a safety profile similar to placebo. The findings are being prepared to support Edding's dossier for seeking regulatory approval of VASCEPA in Mainland China.

The EDPC003R01 trial was a multi-center, randomized, double-blind, placebo-controlled, 12-week pivotal study in adult patients in China with qualifying fasting triglyceride (TG) levels greater than or equal to 500 mg/dL and less than or equal to 2000 mg/dL. The median baseline TG levels in the study were 812 mg/dL and 837 mg/dL for the patients assigned to placebo (n=123) and 4 grams per day of VASCEPA (n=122), respectively. Prior to randomization into the 12-week double-blind treatment period, all patients underwent a six- to eight-week washout period of lipid altering drugs, as well as diet and lifestyle stabilization.

The study's primary endpoint, the percent change in TG levels from baseline to week 12, was met for the 4 gram per day VASCEPA dose group. The patient group assigned to 4 grams per day of VASCEPA showed a statistically significant median TG decrease of 19.9% ($p<0.001$) compared to placebo at the end of the 12-week treatment period.

Consistent with Amarin's MARINE study in a similar patient population, the 4 gram per day dose of VASCEPA in the EDPC003R01 trial did not result in a significant median increase from baseline in low-density lipoprotein cholesterol (LDL-C) compared to placebo at the end of the 12-week treatment period. The primary results of MARINE were published in the *American Journal of Cardiology*[1] in June 2011. Results from the MARINE study were the basis for VASCEPA's initial approval in the United States for triglyceride lowering before the successful results of the REDUCE-IT ® cardiovascular outcomes study.

Importantly, the VASCEPA 4 gram per day dose in EDPC003R01 appeared to be well-tolerated with a safety profile similar to placebo. There were no treatment-related serious adverse events in the EDPC003R01 study.

"We are proud to share news of these positive data from our partner's pivotal Phase 3 clinical study of VASCEPA in China. Elevated triglycerides are a known marker of risk for pancreatitis and for cardiovascular disease. The statistically significant reduction in TG levels seen with the VASCEPA 4 gram per day dose in the study highlights its potential to address an unmet medical need in China, where hypertriglyceridemia is on the rise," said Steven Ketchum, Ph.D., senior vice president and president, research & development and chief scientific officer at Amarin. "This pivotal study in China mirrored Amarin's MARINE study in patients from the United States and other countries, and we are pleased that the data show consistency across the Chinese and non-Chinese study populations. With these favorable data, we now look forward to supporting our partner, Edding, in compiling and submitting its dossier at the earliest possible opportunity for regulatory review in China."

"We are very pleased that the Phase III clinical study of VASCEPA in Mainland China has achieved positive results. Cardiovascular (CV) disease is the largest cause of death in China with significant unmet needs to address. Prevention and treatment of CV diseases is one of the major initiatives promoted by Health China 2030. VASCEPA is anticipated to be launched to further address these pressing needs. We will try our best to promote VASCEPA to market as soon as possible in order to benefit more Chinese patients," said Mr. Xin Ni, founder, chairman and CEO of Edding. "VASCEPA has huge commercial potential in the fast-growing Chinese market. We will work with Amarin to submit the new drug application as soon as possible to bring this cross-era innovative drug to China."

Amarin intends to support Edding in its pursuit of an appropriate label for VASCEPA in China reflecting the results of EDPC003R01 and all other available data supporting the safety and efficacy of VASCEPA.

About Edding
Edding is a leading integrated pharmaceutical company in China. Edding's vision is to become a leading 'Global for China' pharmaceutical company focusing on three core therapeutic areas, namely anti-infectives, cardiovascular disease and respiratory system, by leveraging Edding's market-tested full value chain capabilities. For more information about Edding, visit www.eddingpharm.com.

About Hypertriglyceridemia in China
There were approximately 180.4 million hypertriglyceridemia (HTG) patients in China in 2019, representing approximately 20.2% of the adult population. Among all HTG patients in China, there were approximately 9 million adults who had very high TG levels (≥500 mg/dL). In 2019, there were approximately 36.1 million statin-treated adult patients in China with elevated TG levels (≥150 mg/dL) and either established CVD or diabetes mellitus and two or more additional risk factors for CVD, the addressable patients of the FDA-approved indication for reducing CV events of VASCEPA in China.

About Amarin
Amarin Corporation plc is a rapidly growing, innovative pharmaceutical company focused on developing and commercializing therapeutics to cost-effectively improve cardiovascular health. Amarin's lead product, VASCEPA ® (icosapent ethyl), is available by prescription in the United States,

Canada, Lebanon and the United Arab Emirates. VASCEPA is not yet approved and available in any other countries. Amarin, on its own or together with its commercial partners in select geographies, is pursuing additional regulatory approvals for VASCEPA in China, Europe and the Middle East. For more information about Amarin, visit www.amarincorp.com.

About VASCEPA® (icosapent ethyl) Capsules
VASCEPA (icosapent ethyl) capsules are the first-and-only prescription treatment approved by the FDA comprised solely of the active ingredient, icosapent ethyl (IPE), a unique form of eicosapentaenoic acid. VASCEPA was initially launched in the United States in 2013 based on the drug's initial FDA approved indication for use as an adjunct therapy to diet to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. Since launch, VASCEPA has been prescribed over eight million times. VASCEPA is covered by most major medical insurance plans. The new, cardiovascular risk indication for VASCEPA was approved by the FDA in December 2019.

Indications and Limitation of Use
VASCEPA is indicated:

- As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and
  - established cardiovascular disease or
  - diabetes mellitus and two or more additional risk factors for cardiovascular disease.
- As an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

Important Safety Information

- VASCEPA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to VASCEPA or any of its components.
- VASCEPA was associated with an increased risk (3% vs 2%) of atrial fibrillation or atrial flutter requiring hospitalization in a double-blind, placebo-controlled trial. The incidence of atrial fibrillation was greater in patients with a previous history of atrial fibrillation or atrial flutter.
- It is not known whether patients with allergies to fish and/or shellfish are at an increased risk of an allergic reaction to VASCEPA. Patients with such allergies should discontinue VASCEPA if any reactions occur.
- VASCEPA was associated with an increased risk (12% vs 10%) of bleeding in a double-blind, placebo-controlled trial. The incidence of bleeding was greater in patients receiving concomitant antithrombotic medications, such as aspirin, clopidogrel or warfarin.
- Common adverse reactions in the cardiovascular outcomes trial (incidence ≥3% and ≥1% more frequent than placebo): musculoskeletal pain (4% vs 3%), peripheral edema (7% vs 5%), constipation (5% vs 4%), gout (4% vs 3%), and atrial fibrillation (5% vs 4%).
- Common adverse reactions in the hypertriglyceridemia trials (incidence ≥1% more frequent than placebo): arthralgia (2% vs 1%) and oropharyngeal pain (1% vs 0.3%).
- Adverse events may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.
- Patients receiving VASCEPA and concomitant anticoagulants and/or anti-platelet agents should be monitored for bleeding.

Key clinical effects of VASCEPA on major adverse cardiovascular events are included in the Clinical Studies section of the prescribing information for VASCEPA as set forth below:

Effect of VASCEPA on Time to First Occurrence of Cardiovascular Events in Patients with Elevated Triglyceride levels and Other Risk Factors for Cardiovascular Disease in REDUCE-IT

	VASCEPA		**Placebo**		**VASCEPA vs Placebo**
	N = 4089 n (%)	**Incidence Rate (per 100 patient years)**	**N = 4090 n (%)**	**Incidence Rate (per 100 patient years)**	**Hazard Ratio (95% CI)**
Primary composite endpoint					
Cardiovascular death, myocardial infarction, stroke, coronary revascularization, hospitalization for unstable angina (5-point MACE)	705 (17.2)	4.3	901 (22.0)	5.7	0.75 (0.68, 0.83)
Key secondary composite endpoint					
Cardiovascular death, myocardial infarction, stroke (3-point MACE)	459 (11.2)	2.7	606 (14.8)	3.7	0.74 (0.65, 0.83)
Other secondary endpoints					
Fatal or non-fatal myocardial infarction	250 (6.1)	1.5	355 (8.7)	2.1	0.69 (0.58, 0.81)

Emergent or urgent coronary revascularization	216 (5.3)	1.3	321 (7.8)	1.9	0.65 (0.55, 0.78)
Cardiovascular death [1]	174 (4.3)	1.0	213 (5.2)	1.2	0.80 (0.66, 0.98)
Hospitalization for unstable angina [2]	108 (2.6)	0.6	157 (3.8)	0.9	0.68 (0.53, 0.87)
Fatal or non-fatal stroke	98 (2.4)	0.6	134 (3.3)	0.8	0.72 (0.55, 0.93)
[1] Includes adjudicated cardiovascular deaths and deaths of undetermined causality. [2] Determined to be caused by myocardial ischemia by invasive/non-invasive testing and requiring emergent hospitalization.					

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

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the potential impact of VASCEPA in clinical use and expectations for regulatory filings and approval submissions. 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 following: uncertainties associated generally with research and development, clinical trials and regulatory reviews. 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. Amarin's forward-looking statements do not reflect the potential impact of significant transactions the company may enter into, such as mergers, acquisitions, dispositions, joint ventures or any material agreements that Amarin may enter into, amend or terminate.

Availability of Other Information About Amarin

Investors and others should note that Amarin communicates with its investors and the public using the company website (www.amarincorp.com), the investor relations website (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.

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[1] Bays HE, Ballantyne CM, Kastelein JJ et al. Eicosapentaenoic Acid Ethyl Ester (AMR101) Therapy in Patients with Very High Triglyceride Levels (from the Multi-center, plAcebo-controlled, Randomized, double-blINd, 12-week study with an open-label Extension [MARINE] Trial). *Am J Cardiol.* 2011;108:682-690.