# Amarin Announces FDA Approval of Vascepa(TM) (icosapent ethyl) Capsules for the Reduction of Triglyceride Levels in Adult Patients With Severe Hypertriglyceridemia

July 26, 2012

*Approval Based on Positive Results From MARINE Study*

*Conference Call Scheduled for Today, July 26th at 7:00 p.m. EDT*

BEDMINSTER, N.J. and DUBLIN, Ireland, July 26, 2012 (GLOBE NEWSWIRE) -- Amarin Corporation plc (Nasdaq:AMRN), a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health, announced today that the U.S. Food and Drug Administration (FDA) has approved Vascepa™ (icosapent ethyl) capsules (formerly known as AMR101) as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (TG greater than or equal to 500mg/dL) hypertriglyceridemia (very high triglycerides). Amarin submitted the New Drug Application (NDA) for the use of Vascepa in this indication in September 2011.

"FDA approval of Vascepa represents the introduction of an important new treatment option for patients with severe hypertriglyceridemia. In Amarin's MARINE clinical trial, Vascepa demonstrated a statistically significant placebo-adjusted reduction in levels of triglycerides without elevation in levels of LDL-C, commonly referred to as 'bad cholesterol,'" stated Joseph Zakrzewski, Chairman and CEO of Amarin. "Amarin continues to anticipate commercial launch of Vascepa early in the first quarter of 2013, and we continue to consider three potential paths for the marketing and sale of the product: an acquisition of Amarin, a strategic collaboration, or self-commercialization, the latter of which could include third-party support. We are now focused on continued commercial preparations for Vascepa which includes, but is not limited to, finalizing the introduction of Vascepa to managed care plans to gain formulary access, building-up inventory levels and coordinating other pre-launch marketing activities."

The efficacy and safety of Vascepa were assessed in Amarin's MARINE clinical trial, a randomized, placebo-controlled, double-blind, parallel-group study of adult patients with very high fasting triglyceride levels, between 500 mg/dL and 2000 mg/dL. At baseline, 25% of patients were on concomitant statin therapy, 28% were diabetics, and 39% of patients had TG levels greater than 750 mg/dL. Patients treated for 12 weeks with the 4 gram dose of Vascepa demonstrated a statistically significant placebo-adjusted median triglyceride reduction of 33% (p &#60 0.001), and did not show an increase in LDL-C levels relative to placebo. Vascepa 4 grams per day also showed statistically significant placebo-adjusted median reductions from baseline in non-HDL-C (total cholesterol less "good cholesterol") of 18%, Total Cholesterol (TC) of 16%, Very Low Density Lipoprotein Cholesterol (VLDL-C) of 29%, and apolipoprotein B (Apo B) of 9%.

The most commonly reported adverse reaction (incidence &#62 2% and greater than placebo) in Vascepa treated patients was arthralgia (joint pain) (2.3% for Vascepa vs. 1.0% for placebo).

The following table shows the changes in major lipoprotein and lipid parameters for the treatment groups:

**Median Baseline and Percent Change from Baseline in Lipid Parameters in Patients with Severe (greater than or equal to 500 mg/dL) Hypertriglyceridemia**

| | Vascepa 4 g/day N=76 | | Placebo N=75 | | |
|---|---|---|---|---|---|
| **Parameter** | **Baseline** | **% Change** | **Baseline** | **% Change** | **Difference (95% Confidence Interval)** |
| TG (mg/dL) | 680 | -27 | 703 | +10 | -33* (-47, -22) |
| LDL-C (mg/dL) | 91 | -5 | 86 | -3 | -2 (-13, +8) |
| Non-HDL-C (mg/dL) | 225 | -8 | 229 | +8 | -18 (-25, -11) |
| TC (mg/dL) | 254 | -7 | 256 | +8 | -16 (-22, -11) |

| | | | | | |
|---|---|---|---|---|---|
| HDL-C (mg/dL) | 27 | -4 | 27 | 0 | -4 (-9, +2) |
| VLDL-C (mg/dL) | 123 | -20 | 124 | +14 | -29** (-43, -14) |
| Apo B (mg/dL) | 121 | -4 | 118 | +4 | -9**(-14, -3) |

% Change= Median Percent Change from Baseline

Difference= Median of [Vascepa % Change — Placebo % Change] (Hodges-Lehmann Estimate)

p-values from Wilcoxon rank-sum test

*p-value &#60 0.001 (primary efficacy endpoint)

**p-value &#60 0.05 (key secondary efficacy endpoints determined to be statistically significant according to the pre-specified multiple comparison procedure)

Apo B = apolipoprotein B; HDL-C = high-density lipoprotein cholesterol; LDL-C = low-density lipoprotein cholesterol; non-HDL-C = non-high-density lipoprotein cholesterol; TC = total cholesterol; TG = triglyceride; VLDL-C = very-low-density lipoprotein cholesterol

Note: All endpoints in the above table for MARINE were statistically significant with the exception of HDL-C.

Amarin has made significant progress in its efforts to expand the patent protection for Vascepa in the United States to at least 2030 with seven patent applications either issued, allowed or in progressed states of prosecution and over 25 additional U.S. applications pending. Amarin is awaiting a decision from FDA as to whether Vascepa will be granted five-year new chemical entity (NCE) or three-year new product marketing exclusivity under the provisions of the Hatch-Waxman amendments to the Federal Food, Drug, and Cosmetic Act. Typically, FDA's determination on the exclusivity of approved products is made public through the posting on FDA's website in the Orange Book. This typically occurs mid-month following the month of an NDA approval.

**About Vascepa™ (icosapent ethyl) capsules**

Vascepa™ (icosapent ethyl) capsules, known in scientific literature as AMR101, is a patented, ultra-pure omega-3 fatty acid product, comprising not less than 96% EPA in a 1 gram capsule.

**IMPORTANT PRESCRIBING INFORMATION**

Vascepa™ (icosapent ethyl) is indicated for use in the United States as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (greater than or equal to 500 mg/dL) hypertriglyceridemia.

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

The effect of Vascepa on cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia levels has not been determined.

The daily dose of Vascepa is 4 grams administered orally. Patients should engage in appropriate nutritional intake and physical activity before receiving Vascepa, which should continue during treatment.

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

**IMPORTANT SAFETY INFORMATION**

Attempts should be made to control any medical problems such as diabetes mellitus, hypothyroidism and alcohol intake that may contribute to the lipid abnormalities. Lipid levels should be consistently abnormal before initiating Vascepa.

Medications affecting coagulation (e.g., anti-platelet agents) should be monitored periodically.

In patients with hepatic impairment, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels should be monitored periodically during therapy. Use with caution in patients with known hypersensitivity to fish and/or shellfish.

The most commonly reported adverse reaction (incidence &#62 2% and greater than placebo) in Vascepa treated patients was arthralgia (joint pain) (2.3% for Vascepa vs. 1.0% for placebo).

**About Severe (greater than or equal to 500 mg/dL) Hypertriglyceridemia**

Severe hypertriglyceridemia refers to a condition in which patients have very high levels of triglycerides (greater than or equal to 500 mg/dL) in the bloodstream. Amarin estimates that approximately 4 million people in the United States have severe

hypertriglyceridemia. According to *The American Heart Association Scientific Statement on Triglycerides and Cardiovascular Disease* (2011), triglycerides provide important information as a marker associated with the risk for heart disease and stroke, especially when an individual also has low high-density lipoprotein cholesterol, or HDL-C (often referred to as "good" cholesterol), and elevated levels of LDL-C (often referred to as "bad" cholesterol). The effect of Vascepa on cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined.

**Conference call for investors**

Amarin will host a conference call and webcast for investors, today at 7:00 p.m. EDT to discuss FDA's approval of Vascepa. The conference call will be webcast live and a link to the webcast may be accessed from the "Events & Presentations" page on the Amarin corporate website at www.amarincorp.com.

To listen to the live call on the telephone, dial 1-877-407-8033 (United States and Canada) or 1-201-689-8033 (International). The conference call ID number is 397905. A replay of the call will be available for 30 days by dialing 1-877-660-6853 (United States and Canada) or 1-201-612-7415 (International), account number 286, conference ID 397905.

**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) is Amarin's first FDA approved product. For more information about Vascepa visit www.vascepa.com. Amarin plans to separately seek approval for the use of Vascepa in the treatment of patients with high triglyceride levels who are also on statin therapy for elevated LDL-C levels, the population studied in Amarin's ANCHOR trial, after Amarin's REDUCE-IT cardiovascular outcomes trial is substantially underway. Like Amarin's MARINE study, each of Amarin's ANCHOR and REDUCE-IT studies is the subject of a Special Protocol Assessment (SPA) agreement with the FDA. For more information about Amarin visit www.amarincorp.com.

The Amarin Corporation plc logo is available at http://www.globenewswire.com/newsroom/prs/?pkgid=13817

**Forward-looking statements**

This press release contains forward-looking statements, including statements about the efficacy, safety and therapeutic benefits of Vascepa, clinical trial results, the clinical importance of certain biomarkers and the impact of Vascepa on such biomarkers, the timing of a commercial launch of Vascepa, the potential additional indications for which FDA marketing approval of Vascepa may be sought and the commercial potential of Vascepa, the potential for an acquisition of Amarin or a strategic collaboration with a third party for the commercialization of Vascepa, the timing and outcome of FDA's review determination of whether Vascepa should be granted new chemical entity or new product marketing exclusivity, the status of patent applications currently under review by the United States Patent and Trademark Office, the coverage and expected expiration dates of those patent applications and issued patents and the ability of Amarin to protect the commercial potential of Vascepa. In particular there can be no assurance that Vascepa will be awarded five-year new chemical entity or three-year new product marketing exclusivity and the FDA may take longer than expected to reach any such determination. Amarin's patent portfolio directed to the formulation and uses of Vascepa is still evolving and some patent applications may not issue prior to commercial launch, if ever. 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 the commercial success of new pharmaceutical products, such as Vascepa; Amarin's ability to negotiate and execute a successful acquisition of Amarin or a strategic collaboration with a third party for the commercialization of Vascepa; Amarin's lack of experience with commercializing pharmaceutical products; risks associated with preparations associated with a commercial launch; the risk that FDA may not grant new chemical entity or new product marketing exclusivity to Vascepa; the risk that FDA may not reach a determination with respect to these matters on the timetable that we expect; the risk that patent applications may not result in issued patents, and that issued patents may not prevent competitors from competing with Vascepa; the risk that competitors may challenge the validity, enforceability or both the validity and enforceability of our patents or seek to design products around our issued patent claims and gain marketing approval for generic versions of Vascepa or branded competitive products based on new clinical studies; and the risk that trade secrets may not be maintained and that circumstances that create manufacturing barriers to entry may not last. A further list and description of these risks, uncertainties and other risks associated with an investment in Amarin can be found in the "Risk Factors" section of Amarin's filings with the U.S. Securities and Exchange Commission, including its most recent Annual Report on Form 10-K and 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 except as required by law.

Amarin's product candidates are in various stages of development and are not available for sale or use outside of approved clinical trials, except as it relates to the FDA approval announced herein. This press release is intended for communication with investors. Nothing in this press release should be construed as marketing the use of such product candidates.

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