Amarin Partner EddingPharm Receives Regulatory Approval for VASCEPA® (Icosapent Ethyl) in Mainland China for Cardiovascular Risk Reduction (CVRR)

July 8, 2024

-- VASCEPA Approved by the National Medical Products Administration (NMPA) To Reduce the Risk of Cardiovascular Events as an Adjunct to Statin Therapy in Adult Patients with Elevated Triglyceride (TG) Levels (≥150 mg/dL) and Other High-Risk Characteristics as Studied in REDUCE-IT --

-- EddingPharm Now Working to Prepare for National Reimbursement and Drug Listing (NRDL) and Enhance the Commercial Launch of VASCEPA Across Mainland China --

DUBLIN and BRIDGEWATER, N.J., July 08, 2024 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) today announced that its commercial partner in Mainland China ("China"), EddingPharm (EDDING), has received regulatory approval for VASCEPA® (icosapent ethyl) from China's National Medical Products Administration (NMPA). NMPA granted approval for VASCEPA to reduce the risk of cardiovascular events as an adjunct to statin therapy in adult patients with elevated and high triglycerides (≥150mg/dL) and established cardiovascular disease or diabetes mellitus with ≥2 other cardiovascular disease risk factors, combined with hypertriglyceridemia.

Following approval by NMPA, EDDING is working to include VASCEPA on the National Reimbursement Drug Listing (NRDL) and augment the ongoing commercial launch of VASCEPA in China to include the CVRR indication. The NRDL is updated annually and serves as the primary pathway for public reimbursement of pharmaceutical products in China, covering 98% of the Chinese population. Inclusion on the NRDL provides full or partial reimbursement at the national level. Products included in this listing can be prescribed from public hospitals in China.

According to a recent report on cardiovascular health and disease in China,[i] cardiovascular disease (CVD) accounted for 44-47% of all death in urban and rural areas in China, meaning two out of every five deaths were due to CVD. It is estimated that 330 million patients suffer from CVD in China,[i] and that China has one of the highest CVD death rates in the world.[ii] According to the World Heart Federation, cardiovascular events, such as ischemic heart disease and stroke, are projected to increase by 50 percent among the population in China between 2010 and 2030 (based on population aging and growth alone).[ii]

"We congratulate our partner, EDDING, on the regulatory approval of VASCEPA for cardiovascular risk reduction in China, as this marks an important step in helping broaden access to this novel treatment for patients across that country," said Steven Ketchum, Ph.D., President, Research & Development and Chief Scientific Officer, Amarin. "This milestone is a major step forward to help ensure that the unique benefits of VASCEPA are accessible to patients throughout the world. We look forward to EDDING's continued progress in introducing VASCEPA to patients at-risk for a cardiovascular event across China."

"The approval of the CVRR indication will allow many patients with atherosclerotic disease (ASCVD) in China to benefit from this innovative drug," said EDDING. "In the future, we will continue to expand the application of VASCEPA® in the management of cardiovascular diseases to meet the unmet clinical needs of more Chinese patients."

As part of the approval, NMPA has requested that EDDING conduct a post-approval study after the product is marketed to further verify the efficacy of the product to reduce the risk of cardiovascular events in Chinese patients and provide a post-approval study report to conduct a life-cycle benefit-risk assessment at the time of product renewal. Product renewal is required five years post the approval of the product.

Under the partnership agreement, EDDING is responsible for development and commercialization activities in the China territory and associated expenses. Amarin provides development assistance and is responsible for supplying finished bulk product. Based upon the NMPA approval for the CVRR indication, Amarin will earn a regulatory milestone payment in the amount of $15 million. EDDING will also pay Amarin tiered double-digit percentage royalties on net sales of VASCEPA in the territory. Amarin will supply product to EDDING under negotiated supply terms.

About Amarin

Amarin is an innovative pharmaceutical company leading a new paradigm in cardiovascular disease management. We are committed to increasing the scientific understanding of the cardiovascular risk that persists beyond traditional therapies and advancing the treatment of that risk for patients worldwide. Amarin has offices in Bridgewater, New Jersey in the United States, Dublin in Ireland, Zug in Switzerland, and other countries in Europe as well as commercial partners and suppliers around the world.

About VASCEPA®/VAZKEPA® (icosapent ethyl) Capsules

VASCEPA capsules are the first prescription treatment approved by the U.S. Food and Drug Administration (FDA) comprised solely of the active ingredient, icosapent ethyl, a unique form of eicosapentaenoic acid. VASCEPA was launched in the United States in January 2020 as the first and only drug approved by the U.S. FDA for treatment of the studied high-risk patients with persistent cardiovascular risk after statin therapy. 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 more than 20 million times. VASCEPA is covered by most major medical insurance plans. In addition to the United States, icosapent ethyl is approved and sold in Canada, Lebanon, and the United Arab Emirates. In Europe, in March 2021 marketing authorization was granted to icosapent ethyl in the European Union for the reduction of risk of cardiovascular events in patients at high cardiovascular risk, under the brand name VAZKEPA. VAZKEPA is being commercialized in multiple European countries, including England, Wales, Spain, Sweden and Finland.

United States

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.

FULL U.S. FDA-APPROVED VASCEPA **PRESCRIBING INFORMATION** CAN BE FOUND AT **WWW.VASCEPA.COM**.

Europe

For further information about the Summary of Product Characteristics (SmPC) for VAZKEPA® in Europe, please **click here**.

Globally, prescribing information varies; refer to the individual country product label for complete information.

Forward-Looking Statements

This press release contains forward-looking statements which are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including beliefs about the regulatory approval of VASCEPA in China and the potential impact in that territory; Amarin's overall efforts to expand access and reimbursement to VAZKEPA across global markets; and the overall potential and future success of VASCEPA/VAZKEPA generally. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. 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 Amarin's annual report on Form 10-K for the full year ended 2022. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date they are made. Amarin undertakes no obligation to update or revise the information contained in its forward-looking statements, 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

Amarin communicates with its investors and the public using the company website (www.amarincorp.com) and the investor relations website (investor.amarincorp.com), including but not limited to investor presentations and 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.

Amarin Contact Information

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[i] The Writing Committee of the Report on Cardiovascular Health and Diseases in China. Report on Cardiovascular Health and Diseases in China 2021: An Updated Summary[J]. *Biomedical and Environmental Sciences*, 2022, 35(7): 573-603. doi: 10.3967/bes2022.079

[ii] World Heart Federation Fact Sheet: Cardiovascular Disease in China. chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://world-heart-federation.org/wp-content/uploads/2017/05/Cardiovascular_diseases_in_China.pdf