



Amarin Partner HLS Therapeutics Completes Reimbursement Negotiations with Pan-Canadian Pharmaceutical Alliance (pCPA) for VASCEPA® (icosapent ethyl)

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DUBLIN, Ireland and BRIDGEWATER, N.J., April 26, 2022 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) announced today its partner HLS Therapeutics has completed negotiations with Canada's pan-Canadian Pharmaceutical Alliance (pCPA) for the terms and conditions under which VASCEPA® (icosapent ethyl) would qualify for public market reimbursement in Canada. Following these negotiations, HLS has signed a Letter of Intent (LOI) which allows HLS to work with all participating provincial jurisdictions to secure coverage from publicly funded drug plans across Canada, and for VASCEPA to potentially be added to their respective plans.

"The completion of pCPA's assessment regarding reimbursement represents an important milestone towards advancing the potential reach of therapies across Canada," said Karim Mikhail, president & chief executive officer, Amarin Corporation. "We look forward to continued efforts to secure coverage across the various Canadian jurisdictions, which would significantly increase access to VASCEPA for statin-treated patients with established cardiovascular disease and elevated triglycerides across Canada."

In September 2017, Amarin and HLS Therapeutics entered into an exclusive commercialization agreement between the parties to register, commercialize and distribute VASCEPA capsules in Canada. Under the agreement, HLS is responsible for regulatory and commercialization activities and associated costs. Amarin is responsible for providing assistance towards local filings, supplying finished product and maintaining intellectual property. Prior to the study's completion, Amarin had also been responsible for continuing the development and funding of REDUCE-IT®. Terms of the agreement include up-front and milestone payments to Amarin of up to US\$65.0 million. These payments include a non-refundable upfront payment of US\$5.0 million, which Amarin received when the agreement was reached, as well as development, regulatory and sale-based milestones totaling up to an additional US\$60.0 million. The agreement also provides for HLS to pay Amarin tiered double digit royalties on net sales of VASCEPA in Canada. Amarin is obligated to supply finished product to HLS under negotiated supply terms. The agreement for supply and commercialization is for Canada only and includes all Canadian provinces.

About Amarin

Amarin is an innovative pharmaceutical company leading a new paradigm in cardiovascular disease management. From our foundation in scientific research to our focus on clinical trials, and now our commercial expansion, we are evolving and growing rapidly. 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. We are committed to increasing the scientific understanding of the cardiovascular risk that persists beyond traditional therapies and advancing the treatment of that risk.

About VASCEPA® (icosapent ethyl) Capsules

VASCEPA (icosapent ethyl) capsules are the first-and-only prescription treatment approved by the U.S. Food and Drug Administration (FDA) comprised solely of the active ingredient, icosapent ethyl (IPE), 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 over ten million times. VASCEPA is covered by most major medical insurance plans. In addition to the United States, VASCEPA 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®.

Indications and Limitation of Use (in the United States)

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 $\geq 3\%$ and $\geq 1\%$ 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 $\geq 1\%$ 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.

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 potential for VASCEPA (marketed as VASKEPA in Europe); beliefs about icosapent ethyl (IPE)'s role concerning patients suffering from cardiovascular disease (CVD) and impacts on the risk of heart attack, stroke or other fatal or non-fatal cardiovascular events for patients who suffered a prior heart attack, as well as general beliefs about the safety and effectiveness of VASCEPA. 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 2021. 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 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, 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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