Amarin Receives Positive Recommendation from United Kingdom's (UK) National Institute for Health and Care Excellence (NICE) for Reimbursement of VAZKEPA® (icosapent ethyl)

June 10, 2022

UK's NICE issued its draft Final Appraisal Document (FAD) recommending the use of VAZKEPA ® (icosapent ethyl) in England and Wales to reduce the risk of cardiovascular (CV) events in adult statin-treated patients at high CV risk who have elevated triglycerides (≥150 mg/dL [≥ 1.7 mmol/L]) and established cardiovascular disease (eCVD) [1,2]

Positive reimbursement recommendation follows the recent national reimbursement for VAZKEPA in Sweden and marks another major milestone in the company's European growth strategy

DUBLIN, Ireland and BRIDGEWATER, N.J., June 10, 2022 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) today announces that the UK's National Institute for Health and Care Excellence (NICE) is recommending icosapent ethyl (marketed under the brand name VAZKEPA ®) for reimbursement and use across the National Health Service (NHS) in England and Wales to reduce the risk of cardiovascular (CV) events in adult statin-treated patients at high cardiovascular risk who have elevated triglycerides (≥150 mg/dL [≥ 1.7 mmol/L]), LDL-C levels >1.04 mmol/L (and ≤ 2.60 mmol/L) and established cardiovascular disease (eCVD), at a price of £144.21 per 120 soft capsules (i.e. 30-day supply; equivalent of approximately 170 EUR or 181 USD*).[1,2]

"We are extremely pleased with today's positive recommendation by NICE," said Karim Mikhail, president and chief executive officer. "This is another important step forward in successfully executing our European growth strategy, and considering that the UK has historically served as a reference market with regard to Health Technology Assessments, it is a major step toward unlocking the company's multi-billion-dollar revenue opportunity outside of the U.S.**"

Cardiovascular disease ranks as one of the UK's leading causes of death [3]. More than six million people live with cardiovascular disease in England, costing the NHS around £7.4 billion each year[3,4]. VAZKEPA represents an important scientific innovation for reducing cardiovascular risk in eligible patients across England and Wales, supported by the clinical data from the landmark REDUCE-IT® cardiovascular outcome study[5].

The Final Appraisal Document (FAD) is part of NICE's Health Technology Appraisal (HTA) process aimed at making recommendations on both the clinical and cost effectiveness of medicines and treatments in England to help ensure that the NHS uses its resources fairly and cost-effectively. Today's FAD represents the NICE appraisal committee's draft final guidance related to the use of icosapent ethyl within the NHS in England. NICE's final guidance is expected to be published on the 13th of July 2022, after which all local NHS formularies are expected to make the product available within 3 months. Based on a collaboration with the Welsh Government and the *All Wales Medicines Strategy Group* (AWMSG), the final NICE guidances will also apply to Wales and be implemented across the NHS in Wales.

"This positive recommendation is the outcome of many months of constructive scientific discussions with multiple stakeholders and a detailed systematic review of clinical and economic evidence," commented Laurent Abuaf, senior vice president and president Amarin Europe. "Following Sweden, this is now the second Health Technology Assessment in Europe that recognizes the potential value of VAZKEPA for strengthening cardiovascular care in England and Wales, following a very rigorous clinical and economic evaluation process. We look forward to working with all relevant stakeholders in the NHS to offer this important new treatment option to eligible cardiovascular patients across these countries in the UK."

In parallel, Amarin continues to progress well with its reimbursement discussions in the other European markets and remains on track to receive pricing decisions in up to eight countries with plans to launch VAZKEPA in up to six European countries this year.

**Based on exchange rate of EUR and USD as of the date of this release.*
*** U.S. Dollar*

About Amarin®
Amarin is an innovative pharmaceutical company leading a new paradigm in cardiovascular disease management. From our scientific research foundation 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 rethinking cardiovascular risk through the advancement of scientific understanding of the impact on society of significant residual risk that exists beyond traditional therapies, such as statins for cholesterol management.

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 over 18 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, Germany 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. In April 2021 marketing authorization for VAZKEPA (icosapent ethyl) was granted in Great Britain. The Great Britain Marketing Authorization for VAZKEPA applies to England, Scotland and Wales.

United Kingdom
Indication & Important Safety Information

VAZKEPA® (Icosapent Ethyl) 998 mg soft capsules
This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects.

Prescribers should refer to the Summary of Product Characteristics (SmPC) before prescribing.

Indication: Vazkepa is indicated to reduce the risk of cardiovascular events in adult statin-treated patients at high cardiovascular risk with elevated triglycerides (≥150 mg/dL;≥ 1.7 mmol/L) and either: established cardiovascular disease, or diabetes and at least one other cardiovascular risk factor.

Dosage: Adults: two 998 mg capsules twice daily. Oral administration, taken with or following a meal. Swallow capsules whole. Do not break, crush, dissolve, or chew. Elderly (≥ 65 years): No dose adjustment necessary based on age. Renal impairment: No dose reduction is recommended. Hepatic impairment: No dose reduction is recommended.

Contraindications: Hypersensitivity to the active substance, soya, peanut or to any of the excipients.

Special warnings and precautions: Allergies to fish/shellfish: Vazkepa is obtained from fish oil. It is not known whether patients with allergies to fish and/or shellfish are at increased risk of an allergic reaction to Vazkepa. Vazkepa should be used with caution in patients with known hypersensitivity to fish and/or shellfish. Hepatic impairment: In patients with hepatic impairment, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) concentrations should be monitored as clinically indicated before the start of treatment and at appropriate intervals during treatment. Atrial fibrillation or flutter: Vazkepa was associated with an increased risk of atrial fibrillation or flutter requiring hospitalisation in a double-blind placebo-controlled trial. The incidence of atrial fibrillation was greater in patients with a previous history of atrial fibrillation or flutter. Patients, particularly those with a relevant medical history, should be monitored for clinical evidence of atrial fibrillation or atrial flutter. Electrocardiographic evaluation should be performed when clinically indicated. Bleeding: Treatment with Vazkepa has been associated with an increased incidence of bleeding. Patients taking Vazkepa in combination with antithrombotic agents, i.e., antiplatelet agents, including acetylsalicylic acid, and/or anticoagulants, may be at increased risk of bleeding and should be monitored periodically.

Interactions: Vazkepa was studied with the following medicinal products which are typical substrates of cytochrome P450 enzymes: omeprazole, rosiglitazone, warfarin and atorvastatin. No interactions were observed.

Pregnancy / lactation: Limited human data on use during pregnancy are available. Use of Vazkepa during pregnancy should be avoided unless the benefit of use outweighs the potential risk to the foetus. It is not known whether Vazkepa is excreted in human milk. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Vazkepa therapy considering the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Side effects: Refer to SmPC for full list of undesirable effects. Very common (≥1/10): bleeding; Common (≥1/100 to <1/10): gout, atrial fibrillation or flutter, constipation, eructation, rash, musculoskeletal pain, peripheral oedema; Uncommon (≥1/1000 to <1/100): hypersensitivity, dysgeusia. Not Known: pharyngeal swelling.

Legal Category: Prescription only medicine (POM).

Pack quantities: Vazkepa is available in HDPE bottles containing 120 soft capsules.

Marketing Authorisation Holder: Amarin Pharmaceuticals Ireland Limited, 88 Harcourt Street, Dublin 2, D02DK18 Ireland

Marketing Authorisation Numbers: Great Britain: PLGB 51241/0002 Northern Ireland: EU/1/20/1524/001

Date of last revision: April 2022

Adverse events should be reported. Reporting forms and information can be found at **https://yellowcard.mhra.gov.uk/**
Adverse events should also be reported to Amarin Pharmaceuticals Ireland Limited:
Tel: **0800 0478 673** or e-mail: **AmarinConnect@amarincorp.eu**

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.

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

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, but not limited to, beliefs about the market potential for VAZKEPA; expectations regarding performance such as prescription growth and market access for VAZKEPA; plans for Amarin's go-to-market model in the UK; the timing and outcome of related reimbursement decisions and commercial launches in the UK and elsewhere; and expectations for the timing, effectiveness and outcome of promotional activities. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties, including, with respect to the UK, Amarin's ability to effectively commercialize VAZKEPA and maintain or grow market share will depend in part on Amarin's ability to continue to effectively finance its business; Amarin's ability to create and increase market demand and achieve broad market acceptance for VAZKEPA; to develop and maintain a consistent source of commercial supply at a competitive price; and to comply with legal and regulatory requirements in connection with the sale and promotion of VAZKEPA. Among the factors that could cause actual results to differ materially from those described or projected include the following: the risk that Amarin has overestimated the market potential for VAZKEPA; risks associated with Amarin's expanded enterprise; uncertainties associated generally with research and development, clinical trials and related regulatory approvals; and the risk that sales may not meet expectations and related costs may increase beyond expectations. 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 year ended December 31, 2021, filed on or about the date hereof. 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
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, 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] National Institute for Health and Care Excellence. Final Draft Guidance: Icosapent ethyl with statin therapy for reducing the risk of cardiovascular events in people with raised triglycerides [ID3831]. NICE; 2022. Available from: https://www.nice.org.uk/guidance/gid-ta10736/documents/final-appraisal-determination-document. Accessed June 2022.

[2] VAZKEPA (icosapent ethyl) Summary of Product Characteristics (April 2022) https://www.medicines.org.uk/emc/product/12964/smpc#gref. Accessed May 2022.

[3] British Heart Foundation. UK Factsheet January 2022. https://www.bhf.org.uk/-/media/files/research/heart-statistics/bhf-cvd-statistics---uk-factsheet.pdf. Accessed May 2022.

[4] Public Health England. Health matters: preventing cardiovascular disease. https://www.gov.uk/government/publications/health-matters-preventing-cardiovascular-disease/health-matters-preventing-cardiovascular-disease. Accessed May 2022.

[5] Bhatt DL, Steg PG, Miller M, et al. Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglyceridemia. N Engl J Med. 2019;380(1):11-22.