NICE Issues Final Guidance for Reimbursement Making VAZKEPA® (icosapent ethyl) Available Across the NHS in England & Wales

July 13, 2022

-- Newly published final guidance by the National Institute for Health and Care Excellence (NICE) in the UK confirms its prior draft recommendation for 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]), controlled LDL-C between 1.04 mmol/L - 2.60 mmol/L and established cardiovascular disease (eCVD).[1,2] --

DUBLIN, Ireland and BRIDGEWATER, N.J., July 13, 2022 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ: AMRN) today announced that NICE has issued its final guidance recommending VAZKEPA® (icosapent ethyl) for reimbursement and use across the National Health Service (NHS) in England and Wales to help reduce the risk of major CV events in high-risk statin-treated patients with eCVD, at a price of £144.21 per 120 soft capsules (i.e. 30 day supply; the equivalent of approximately 171 EUR or 172 USD*).

This announcement marks a major milestone for Amarin globally and in the UK, as following final guidance, all local NHS formularies in England and Wales will need to make VAZKEPA available within 90 and 60 days, respectively. Today's final guidance also further supports the successful execution of Amarin's European growth strategy, and the Company's efforts to unlock the multi-billion-dollar revenue opportunities for the product outside of the U.S.**

Karim Mikhail, president and chief executive officer of Amarin said, "Receiving this final guidance from NICE is a significant moment, as it is another important step in our international expansion. Our teams in Europe are working incredibly hard to ensure a successful launch of VAZKEPA, so we can help transform the lives of CV patients across the region and move closer to realizing our bold vision of reaching the day when heart disease is no longer a leading cause of death."

The publication of the final guidance supports the growing recognition of VAZKEPA's clinical benefits. It is the last step in the NICE Health Technology Appraisal (HTA) process, used to assess the clinical benefits and cost-effectiveness of medicines and treatments in England to ensure the NHS uses its resources fairly and cost-effectively. Based on the collaborative relationship between the Welsh Government and the All-Wales Medicines Strategy Group (AWMSG), the final NICE guidance will also be implemented across the NHS in Wales, in line with the devolved powers of the Welsh Assembly.

Commenting on today's news, Laurent Abuaf, senior vice president and president, Amarin Europe said, "We have a once in a generation opportunity to transform the lives of cardiovascular patients across Europe, and today's announcement regarding NICE's final guidance will help us realize that mission in one of our key markets. Following the successful completion of the HTA assessment in the UK, and the positive reimbursement guidance, our local teams in every country in Europe will be inspired by how the UK will be prioritizing access to local health economies. Our teams in the UK will of course work tirelessly to make this medicine available across the whole territory in the coming months."

Off the back of this success, Amarin continues to drive forward reimbursement discussions in other major 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 VAZKEPA® (icosapent ethyl) Capsules

VAZKEPA capsules are the first prescription treatment comprised solely of the active ingredient, icosapent ethyl, a highly purified form of eicosapentaenoic acid. Since launch, icosapent ethyl has been prescribed more than 18 million times globally. In addition to the United States, icosapent ethyl is approved and sold in Canada, Lebanon and the United Arab Emirates under the brand name VASCEPA. In March 2021, marketing authorization was granted to icosapent ethyl in the European Union under the brand name VAZKEPA 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 established cardiovascular disease or diabetes and at least one other cardiovascular risk factor[3]. In April 2021 marketing authorization for VAZKEPA (icosapent ethyl) was granted in Great Britain (applying to England, Scotland and Wales). VAZKEPA (icosapent ethyl) is currently approved and sold in Europe in Germany, Sweden, Denmark and the UK.

EU Product Information

VAZKEPA® SOFT CAPSULES
This medicine is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

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.

Further information about the Summary of Product Characteristics (SmPC) for VAZKEPA® in Europe, can be found here.

Globally, prescribing information varies; please 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 U.S. 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, U.S. 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 U.S. Securities Act of 1933.

Amarin Contact Information

Media Inquiries:

Mark Marmur
Communications Amarin Corporation plc
PR@amarincorp.com

Investor Inquiries:
Lisa DeFrancesco
Investor Relations Amarin Corporation plc
investor.relations@amarincorp.com

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1 National Institute for Health and Care Excellence. Final Guidance: Icosapent ethyl with statin therapy for reducing the risk of cardiovascular events in people with raised triglycerides [ID3831]. NICE; 2022. https://www.nice.org.uk/guidance/gid-ta10736/documents/final-appraisal-determination-document. Accessed July 2022.
2 VAZKEPA (icosapent ethyl) Summary of Product Characteristics (April 2022) https://www.medicines.org.uk/emc/product/12964/smpc#gref. Accessed July 2022.
3 Vazkepa® (icosapent ethyl): Summary of Product Characteristics. Available from: https://www.ema.europa.eu/en/documents/product-information/vazkepa-epar-product-information_en.pdf [accessed July 2022]