



Amarin Receives National Reimbursement for VAZKEPA® in Italy

December 16, 2024

-- Italian Health Authorities Approve VAZKEPA® (icosapent ethyl) for National Reimbursement to Reduce Cardiovascular Risk in Eligible High-Risk Patients¹ --

-- Italy is the Third EU5 Market to Grant National Reimbursement; Ninth National Reimbursement for VAZKEPA® Overall in Europe --

-- European Progress Has Advanced Patient Access: Countries That Have Provided Access to VAZKEPA Now Account for More Than 50% of the Total Established Cardiovascular Disease (eCVD) Population in Western Europe --

-- Italy Approval Further Validates the Progress Made by the Company Following Execution of a New Strategy Implemented in 2023 --

DUBLIN and BRIDGEWATER, N.J., Dec. 16, 2024 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), today announced that Italy's National Health Service (NHS) approved VAZKEPA® for national reimbursement to reduce cardiovascular risk in eligible high-risk patients, as published in the Official Journal of the Italian Republic (i.e. *Gazzetta Ufficiale della Repubblica Italiana*)¹.

As in most European countries, cardiovascular disease is the leading cause of death and hospitalization in Italy, with over 217,000 deaths² per year and over 107,000 hospitalizations annually due to myocardial infarction alone³. One in five cardiovascular patients experience another cardiovascular event within 12 months of their first event⁴, highlighting the urgent need for new treatment options to reduce cardiovascular risk.

Commenting on the reimbursement, Dr Aldo Pietro Maggioni, Director of the Study Center of the Italian Association of Hospital Cardiologists (*centro studi ANMCO*) stated: "Patients with established cardiovascular disease and elevated triglycerides, despite a well-managed LDL-C level, still have a higher likelihood of experiencing subsequent CV events, as there are currently no effective therapies for this patient phenotype. The Italian regulatory authority addressed this clinical need by authorizing the reimbursement of icosapent ethyl which, in the REDUCE-IT study, has shown to reduce cardiovascular death as well as recurrent myocardial infarction, stroke and coronary revascularization. The reimbursement approval of icosapent ethyl offers clinicians an additional effective treatment option for high cardiovascular risk patients."

Italian Approval Underscores Impact & Progress of New Strategy

As highlighted in Amarin's [Investor Day](#) in November, in 2023 the Company implemented a more focused strategic approach to advance reimbursement, access and commercialization in Europe. This improved strategy has delivered meaningful results. Over the last 18 months, and factoring in the Italy approval, the Company has now secured national reimbursement in 3 of the EU5 markets and nine European markets overall. This represents more than 50% of the current total eCVD eligible patient population across Western Europe.

Additionally, as a reminder, the intellectual property for VAZKEPA in Europe has recently been extended to 2039. Unlike the US, there is no "skinny label" risk that permits competitive entry prior to the 2039 expiration of the Company's patents for the cardiovascular risk indication for VAZKEPA.

Commenting on the Italian approval, Aaron Berg, President & CEO of Amarin, said, "Today is an important day, not only for Amarin, but for patients in Italy, the third largest economy in Europe. We appreciate that the Italian authorities have recognized the strength of the clinical data supporting VAZKEPA and affirming the potential impact it can have for the many eCVD patients across all of Italy."

Commenting on the Company's progress in Europe and globally, Berg said, "Today's announcement is another important step that builds upon the strong foundation to capitalize on the tremendous untapped opportunity for VAZKEPA globally. With recently granted patent protection extending the exclusivity in Europe to 2039, it is still early in the lifecycle with a long runway to generate growth. Backed by strong science validated through the endorsement of over 50 medical societies globally, and with 46 countries that have now approved VASCEPA/VAZKEPA for cardiovascular risk reduction, we know there remains significant potential to benefit millions of patients worldwide. Our focus remains clear: to capitalize on the global value opportunity for VASCEPA/VAZKEPA by getting it into the hands of as many patients as possible. That is our commitment to patients, providers, employees and shareholders."

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.

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 VAZKEPA in Europe); beliefs about icosapent ethyl (IPE)'s role concerning appropriate patients suffering from cardiovascular disease (CVD) and potential population health impact, 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 2023.

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.

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¹ https://www.gazzettaufficiale.it/atto/serie_generale/caricaDettaglioAtto/originario?atto.dataPubblicazioneGazzetta=2024-12-14&atto.codiceRedazionale=24A06678&elenco30giorni=false

² Lstat 2021 - <https://www.istat.it/wp-content/uploads/2024/06/Report-cause-di-morte-Anno-2021.pdf>

³ PNE 2022

⁴ Gargiulo G. et al. 2022