

Amarin And Neopharm Announce Exclusive Commercialization Agreement for VAZKEPA® (Icosapent Ethyl) in Israel

August 8, 2023

-- Agreement Follows Recent Regulatory Approval in Israel of VAZKEPA® to Reduce the Risk of Cardiovascular (CV) Events in Adult Statin-Treated Patients at High CV Risk with Elevated Triglycerides and Other High-Risk Characteristics as Studied in REDUCE-IT --

-- Heart Disease Second Leading Cause of Death in Men and Women Aged 45 and Older in Israel --

DUBLIN, Ireland, BRIDGEWATER, N.J and PETAH TIKVA, ISRAEL, Aug. 08, 2023 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) and Neopharm Israel announced today that the two companies have entered into an exclusive marketing and commercialization agreement for VAZKEPA® (icosapent ethyl) in the State of Israel, Gaza, West Bank and the territories of the Palestinian Authority. VAZKEPA capsules are the first prescription treatment comprised solely of the active ingredient, icosapent ethyl, a highly purified form of eicosapentaenoic acid.

"We are excited to announce this agreement with Neopharm, a leading provider of pharmaceutical commercialization in Israel," said Patrick Holt, President & CEO, Amarin. "Neopharm is well-positioned with its commercial capabilities, as well as its pedigree and experience in cardiology and related disease categories, to enable access to this important medicine for patients in Israel."

"The addition of VAZKEPA to our portfolio and the opportunity to serve and improve the lives of Israeli statin-treated patients suffering from cardiovascular events is a privilege," said Efi Shnaidman, General Manager of Neopharm Israel. "We look forward to working together with Amarin in making VAZKEPA available and accessible to patients."

The agreement follows Israel's Ministry of Health (MOH) Pharmaceuticals Division granting regulatory approval to VAZKEPA (icosapent ethyl). The MOH issued its approval of 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 either established cardiovascular disease or diabetes and at least one other cardiovascular risk factor.

According to data from the Israeli Ministry of Health, heart diseases are the second leading cause of death in Israel, in both men and women, aged 45 and older.¹ Heart disease accounted for about one-sixth of all male and female deaths in recent years in Israel.¹

"The regulatory approval of VAZKEPA in Israel marks continued progress in our effort to bring this product to patients with residual cardiovascular risk around the world," said Steven Ketchum, PhD., President, Research & Development and Chief Scientific Officer, Amarin. "We are proud of this important milestone in that effort, and that patients in Israel will soon be able to access this important therapeutic option to address their residual cardiovascular risk."

Under the terms of the agreement with Neopharm, Amarin has appointed Neopharm as its sole and exclusive distributor of VAZKEPA in the territory to import, register, distribute and commercialize the product, in order to ensure access to patients. Amarin grants Neopharm the right to hold under its own name the Regulatory Approvals and Regulatory filings as the Marketing Authorization Holder for VAZKEPA in this territory. Amarin will be responsible for supplying finished product to Neopharm at a transfer price paid to Amarin.

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 Neopharm

Established in 1941, Neopharm is one of Israel's leading providers of innovative integrated solutions across the pharmaceutical, medical and healthcare markets. Neopharm focuses on the sale and marketing of novel groundbreaking specialty and orphan medications as well as home healthcare services in Israel via partnerships with the world's leading multinational bio-pharma companies. Neopharm is the partner-of-choice and one-stop-shop for multinational bio-pharma companies seeking to enter or expand their business in the Israeli pharmaceutical, medical and biotechnology markets and is proud of its best-in-class platform, reputation and track-record of success for launching and marketing groundbreaking novel therapies in Israel.

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 over 18 million times. In addition to the United States, icosapent ethyl is approved and sold in Canada, Lebanon, 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 factor¹. 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 Sweden, Denmark, Finland, Austria, and the UK.

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 Amarin's entry into Israel and continued expansion in other key international markets; Amarin's partnership discussions for Israel; the potential pricing and reimbursement for VAZKEPA in Israel beginning in 2024; and the overall potential and future success of VASCEPA (marketed as VAZKEPA in Europe) and Amarin 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.

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¹ VAZKEPA® (icosapent ethyl) [Summary of Product Characteristics](#) (Accessed August 2023)

ⁱ Israeli Ministry of Health – Health Information Division. Leading causes of death in Israel 2000 – 2019. https://www.gov.il/BlobFolder/reports/leading-causes-of-death-in-israel/he/files_publications_units_info_CausesOfDeaths2019_Summary.pdf