

# Amarin Outlines New Go-to-Market Strategy to Accelerate VASCEPA® (Icosapent Ethyl) Growth in U.S.

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#### Enables Amarin to Drive Additional Demand, Improve Patient Access & Education and Secure Proper Fulfillment and Reimbursement

DUBLIN, Ireland and BRIDGEWATER, N.J., Sept. 22, 2021 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ: AMRN) today outlined its new Go-to-Market strategy to accelerate growth of VASCEPA<sup>®</sup> (icosapent ethyl) in the United States, which focuses on expanding healthcare professional engagement through a new omnichannel platform, enhancing managed care access and optimizing VASCEPA prescriptions for cardiovascular (CV) risk reduction.

"Amarin is embarking on a transformation to a new, integrated Go-to-Market approach in the U.S., furthering our mission of helping millions of untreated, at-risk patients gain access to VASCEPA," said Karim Mikhail, Amarin's president and chief executive officer. "We are seeing a dramatic shift in how physicians prefer to engage and are applying key learnings from our European launch initiatives as we work to maximize our impact with both healthcare professionals and patients. We continue to believe that there is enormous opportunity for VASCEPA/VAZKEPA in the U.S. and throughout the rest of the world. With this new strategy, we are confident in our ability to drive U.S. growth and realize the full potential of our first-of-its kind product as we continue to execute our global strategic plan to create value for all shareholders."

Aaron Berg, Amarin's executive vice president and president, U.S., added, "Our new Go-to-Market strategy is a more dynamic, nimble and efficient approach to educating healthcare professionals and patients about our product to reduce cardiovascular risk. We believe this strategy will allow Amarin to accelerate VASCEPA prescription growth and drive an increasingly profitable U.S. franchise."

#### **Key Strategic Priorities**

• Expanding Healthcare Provider Engagement: Amarin's omnichannel approach will enhance the Company's reach to healthcare professionals, targeting a far greater number of the almost 700,000 statin prescribers through high frequency, tailored and impactful messaging regarding the significant benefits of VASCEPA for CV risk reduction.

Consistent with this model, Amarin will optimize its U.S. field force and focus on the most productive territories. This will result in a reduction of Amarin's U.S. field force to approximately 300 sales representatives who will remain a critical part of the Company's commercial strategy going forward. Amarin will reinvest the realized net savings towards its expanded educational and promotional efforts.

- Enhancing Managed Care Access: Amarin will continue working with payers to enhance its strong managed care position and further remove barriers to VASCEPA prescriptions to ensure that patients in need of CV risk reduction receive proper therapy. Importantly, several large Commercial and Medicare Part D payers currently cover VASCEPA as the exclusive icosapent ethyl (IPE) product due to its cost-effectiveness.
- Optimizing VASCEPA Prescriptions for CV Risk Reduction: Today, branded VASCEPA remains the only available U.S. Food and Drug Administration (FDA) approved IPE medication for CV risk reduction. To prevent improper generic substitution for this indication, Amarin is continuing to aggressively educate critical stakeholders in the prescribing continuum to ensure proper fulfillment at each step. Additionally, Amarin is evaluating various innovative solutions designed to better manage IPE prescriptions for CV risk reduction.

Mr. Berg concluded, "Our people have always been and remain the foundation of our business. Decisions that impact people are never easy, and we are making every effort to support those employees who are affected by our field force optimization."

## 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, and Zug in Switzerland 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 Cardiovascular Risk

Cardiovascular disease is the number one cause of death in the world. In the United States alone, cardiovascular disease results in 859,000 deaths per year.<sup>1</sup> And the number of deaths in the United States attributed to cardiovascular disease continues to rise. In addition, in the United States there are 605,000 new and 200,000 recurrent heart attacks per year (approximately 1 every 40 seconds). Stroke rates are 795,000 per year (approximately 1 every 40 seconds), accounting for 1 of every 19 U.S. deaths. In aggregate, in the United States alone, there are more than 2.4 million major adverse cardiovascular events per year from cardiovascular disease or, on average, 1 every 13 seconds.

Controlling bad cholesterol, also known as LDL-C, is one way to reduce a patient's risk for cardiovascular events, such as heart attack, stroke or death. However, even with the achievement of target LDL-C levels, millions of patients still have significant and persistent risk of cardiovascular events, especially those patients with elevated triglycerides. Statin therapy has been shown to control LDL-C, thereby reducing the risk of cardiovascular events by 25-35%.<sup>2</sup> Significant cardiovascular risk remains after statin therapy. People with elevated triglycerides have 35% more cardiovascular events compared to people with normal (in range) triglycerides taking statins.<sup>3,4,5</sup>

# 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 ≥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 and other securities laws. Any statements contained herein which do not describe historical facts, including, among others, statements regarding beliefs about Amarin's go-to-market strategy and its ability to accelerate growth of VASCEPA in the United States, including through enhanced managed care access, prescription optimization and capitalizing on existing revenue growth opportunities; beliefs about physician engagement; expectations regarding Amarin's ability to drive U.S. growth, create shareholder value and drive an increasingly profitable franchise; plans regarding Amarin's key strategic priorities, including to expand healthcare provider engagement, enhance managed care access and optimize prescriptions for cardiovascular risk reduction; plans to reduce the Amarin field force and support impacted employees; beliefs that there will be enormous worldwide opportunity for VASCEPA and expectations regarding the full potential of VASCEPA as a first-of-its kind product. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties, which could cause actual results to differ materially from those described or projected herein, including (among others): Amarin may be unsuccessful in implementing its go-to-market strategy or, even if successful, may not achieve the expected results of such efforts; the risk that Amarin has overestimated the market potential for VASCEPA in the United States, Europe and other geographies; the possibility that VASCEPA may not receive regulatory approval in the China region or other geographies on the expected timelines or at all; the risk that additional generic versions of VASCEPA will enter the market and that generic versions of VASCEPA will achieve greater market share and more commercial supply than anticipated, particularly in light of the recent and disappointing

pandemic will continue to impact access to and sales of VASCEPA; risks associated with Amarin's evolving enterprise; uncertainties associated generally with research and development, clinical trials and related regulatory approvals; the risk that sales may not meet expectations and related cost may increase beyond expectations; the risk that patents may be determined to not be infringed or not be valid in patent litigation and applications may not result in issued patents sufficient to protect the VASCEPA franchise. Further, Amarin's ability to effectively commercialize VASCEPA and maintain or grow market share will depend in part on Amarin's ability to continue to effectively finance its business, VASCEPA approval in geographies outside the U.S., efforts of third parties, Amarin's ability to create and increase market demand for VASCEPA through education, marketing and sales activities, to achieve broad market acceptance of VASCEPA, to receive adequate levels of reimbursement from third-party payers, to develop and maintain a consistent source of commercial supply at a competitive price, to comply with legal and regulatory requirements in connection with the sale and promotion of VASCEPA and to secure, maintain and defend its patent protection for VASCEPA. A list of additional risks and uncertainties, and further description of the foregoing risks and uncertainties, associated with an investment in Amarin can be found in Amarin's filings with the U.S. Securities and Exchange Commission, including Amarin's quarterly report on Form 10-Q for the quarter ended June 30, 2021 and subsequent filings with the Commission. 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 (<u>www.amarincorp.com</u>), the investor relations website (<u>investor.amarincorp.com</u>), including but not limited to investor presentations and investor 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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<sup>5</sup> Nordestgaard BG. Triglyceride-rich lipoproteins and atherosclerotic cardiovascular disease - New insights from epidemiology, genetics, and biology.

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<sup>&</sup>lt;sup>1</sup> American Heart Association. Heart Disease and Stroke Statistics—2020 Update: A Report From the American Heart Association *Circulation*. 2020;141:e139-e596.

<sup>&</sup>lt;sup>2</sup> Ganda OP, Bhatt DL, Mason RP, et al. Unmet need for adjunctive dyslipidemia therapy in hypertriglyceridemia management. *J Am Coll Cardiol.* 2018;72(3):330-343.

<sup>&</sup>lt;sup>3</sup> Budoff M. Triglycerides and triglyceride-rich lipoproteins in the causal pathway of cardiovascular disease. Am J Cardiol. 2016;118:138-145.