Amarin Corporation

Amarin Plans to Increase VASCEPA® (icosapent ethyl) Promotion and Education

June 1, 2020

Significant Opportunity Seen as Patient Visits Resume to Emphasize VASCEPA as the First and Only Drug Approved for Its Current Cardiovascular Risk Reduction Indication

DUBLIN, Ireland and BRIDGEWATER, N.J., June 01, 2020 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), today announced that it intends to increase the level and breadth of its promotion and education initiatives regarding VASCEPA® (icosapent ethyl). As early signs emerge of patients returning to physicians' offices, Amarin plans to emphasize its key marketing messages including positioning VASCEPA as the only FDA-approved drug for lowering the persistent cardiovascular risk beyond statin therapy for millions of high-risk patients.

While VASCEPA has been developed and clinically tested for over a decade, it was less than six months ago (December 2019) that the FDA approved VASCEPA for its unique cardiovascular risk reduction indication. Most healthcare professionals and at-risk patients are unaware that VASCEPA is the first and only drug with this important new indication. For this reason, and the emerging return of patients, Amarin believes the opportunity exists for increasing awareness of VASCEPA and its potential to provide an important healthcare solution to reduce cardiovascular risk in high-risk patients.

In the United States alone, someone suffers a heart attack, stroke, or other major adverse event from cardiovascular disease on average every 13 seconds. Cardiovascular disease impacts adults of all ages and is the number one cause of death in the United States. Urgent attention and a proven treatment, such as VASCEPA, is needed for the vast and growing need to reduce the risk of major adverse cardiovascular events in high-risk cardiovascular patients.

Amarin's president and chief executive officer, John Thero, commented, "Particularly in these difficult times, Amarin believes that patients would benefit from receiving preventative healthcare solutions with demonstrated outcomes-based results. VASCEPA is one of those solutions. It is proven to reduce risk, it has been found to be affordable and cost-effective and it is covered by most insurance policies. However, while millions of people are included within the new VASCEPA indication, most are unaware of VASCEPA." He added, "As American society begins to open up again, Amarin currently plans to restore approximately $80 million in educational and promotional spending in 2020 to increase awareness of VASCEPA as an important new treatment recently approved to lower the risk of heart attacks, strokes, and other major adverse cardiovascular events in high risk patients beyond standard of care statin therapy."

Planned promotion and educational efforts include the sponsorship of continuing medical education, social media-based communications, and advertisements on television and other forms of media. Amarin also plans increased sponsorship of investigator-initiated research, such as the recently announced clinical investigation of VASCEPA in the treatment of COVID-19. These initiatives should become increasingly visible in July 2020 and beyond. At the start of 2020, Amarin had intended to commence such expanded promotion in mid-2020 but cancelled such plans following the onset of COVID-19 and the prospects for a potential launch of generic versions of VASCEPA. Amarin's current plans restore most of that intended promotion.

In addition, as the United States reopens from the COVID-19 epidemic, Amarin intends to resume field-based face-to-face interactions with healthcare providers by its sales force, commencing on a pilot scale basis before the end of June 2020, based on current expectations. Assuming that these interactions prove to be helpful and other parts of the country reopen, the company plans to expand such interactions on a phased basis across select geographies. Prescription growth on a year-over-year basis in Q2'20 has, as expected due to COVID-19, been considerably slower than in Q1'20. However, Amarin believes that there are early signs that patient care for chronic conditions, such as treating the risks of cardiovascular disease, is increasing with more patients returning to their healthcare providers for routine medical visits.

Amarin plans to adjust its level of promotion and educational activities upward or downward based on various factors, including whether any generic company takes the risk of launching a generic version of VASCEPA during the patent litigation appeal process and the amount of any product launched. Amarin does not believe generic companies have made the investment of resources, know-how and time to develop sufficient quantities of quality supply to meet current and growing demand. Accordingly, Amarin believes that if any generic determines to launch its product after an FDA approval that any such launch would be limited in scope.

If Amarin wins on its patent litigation appeal the benefits of Amarin's planned increased promotion and education efforts should accrue to both improved patient care and to increased sales of VASCEPA by Amarin. If Amarin loses on the patent litigation appeal, increased VASCEPA usage as a result of increased promotion and education efforts should still benefit patient care. The larger market would potentially be split among branded VASCEPA, a potential authorized generic version of VASCEPA, if then launched by Amarin (which Amarin could launch rapidly if warranted), and generic versions of VASCEPA from third-parties. As noted, Amarin believes any launch of generic versions of VASCEPA by such third parties would be subject to supply limitations. Amarin reiterated that it believes that it has strong arguments in its patent litigation appeal but that it cannot predict the outcome.

Amarin is progressing its plans for international expansion. Those plans are not directly impacted by increased promotion in the United States but could benefit from the company's anticipated expanded educational initiatives.

About Amarin

Amarin Corporation plc is a rapidly growing, innovative pharmaceutical company focused on developing and commercializing therapeutics to cost-effectively improve cardiovascular health. Amarin's lead product, VASCEPA (icosapent ethyl), is available by prescription in the United States, Canada, Lebanon and the United Arab Emirates. Amarin, together with its commercial partners in select geographies, is pursuing additional regulatory approvals for VASCEPA in China, the European Union and the Middle East. For more information about Amarin, visit www.amarincorp.com.

About Cardiovascular Risk

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

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% – but that still leaves a 65-75% risk remaining.[2] People with elevated triglycerides have 35% more cardiovascular events compared to people with normal (in range) triglycerides taking statins.[3,4,5]

About VASCEPA® (icosapent ethyl) Capsules

VASCEPA (icosapent ethyl) capsules are the first-and-only prescription treatment approved by the FDA comprised solely of the active ingredient, icosapent ethyl (IPE), a unique form of eicosapentaenoic acid. 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 eight million times and is covered by most major medical insurance plans. The new, cardiovascular risk indication for VASCEPA was approved by the FDA in December 2019 based on the results of the landmark REDUCE-IT® trial.

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.

Key clinical effects of VASCEPA on major adverse cardiovascular events are included in the Clinical Studies section of the prescribing information for VASCEPA, as set forth below:

Effect of VASCEPA on Time to First Occurrence of Cardiovascular Events in Patients with Elevated Triglyceride levels and Other Risk Factors for Cardiovascular Disease in REDUCE-IT

	VASCEPA		Placebo		VASCEPA vs Placebo
	N = 4089 n (%)	Incidence Rate (per 100 patient years)	N = 4090 n (%)	Incidence Rate (per 100 patient years)	Hazard Ratio (95% CI)
Primary composite endpoint					
Cardiovascular death, myocardial infarction, stroke, coronary revascularization, hospitalization for unstable angina (5-point MACE)	705 (17.2)	4.3	901 (22.0)	5.7	0.75 (0.68, 0.83)
Key secondary composite endpoint					
Cardiovascular death, myocardial infarction, stroke (3-point MACE)	459 (11.2)	2.7	606 (14.8)	3.7	0.74 (0.65, 0.83)
Other secondary endpoints					
Fatal or non-fatal myocardial infarction	250 (6.1)	1.5	355 (8.7)	2.1	0.69 (0.58, 0.81)
Emergent or urgent coronary revascularization	216 (5.3)	1.3	321 (7.8)	1.9	0.65 (0.55, 0.78)
Cardiovascular death [1]	174 (4.3)	1.0	213 (5.2)	1.2	0.80 (0.66, 0.98)
Hospitalization for unstable angina [2]	108 (2.6)	0.6	157 (3.8)	0.9	0.68 (0.53, 0.87)
Fatal or non-fatal stroke	98 (2.4)	0.6	134 (3.3)	0.8	0.72 (0.55, 0.93)

[1] Includes adjudicated cardiovascular deaths and deaths of undetermined causality.

[2] Determined to be caused by myocardial ischemia by invasive/non-invasive testing and requiring emergent hospitalization.

FULL VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT WWW.VASCEPA.COM.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding Amarin plans for increased promotion, educational and research activities in various forms, over specified periods of time and to various degrees, such efforts accruing to benefit Amarin under various scenarios, Amarin's belief in the strength of its arguments in connection with its patent litigation appeal, Amarin's expectations with respect to the potential timing and extent of launch of generic versions of VASCEPA and Amarin's beliefs related to access to supply capacity of icosapent ethyl by generic companies. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: uncertainties associated generally with promotional, educational and research efforts, the launch of generic icosapent ethyl, the availability of supply of generic icosapent ethyl, the extent and impact of any such launch on Amarin's plans and assumptions, the extent of icosapent ethyl supply available to generic companies and risks associated with litigation. 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 its most recent quarterly report on Form 10-Q. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Amarin undertakes no obligation to update or revise the information contained in this press release, 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 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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