Amarin Corporation

Amarin Takes Proactive Steps to Support Public Health Priorities

March 15, 2020

DUBLIN, Ireland and BRIDGEWATER, N.J., March 15, 2020 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), a leader in preventative cardiovascular risk reduction therapy, today announced actions in support of public health initiatives to combat the COVID-19 pandemic.

The COVID-19 pandemic is a significant threat to public health throughout the world. WHO[1], many countries[2], and the majority of states[3] in the United States have recently declared emergencies and implemented strategies designed to contain spread of the virus through social distancing and other methods. Social distancing at the early stages of a pandemic is critical to stem the trajectory of disease proliferation. In support of social distancing, public officials have taken numerous actions: international travel has been restricted, schools have been shut down, public events have been cancelled and group gatherings have been minimized. These steps are being taken to minimize personal interaction as much as possible to stem disease spread and "flatten the curve". In the field of pharmaceutical marketing, increased social contact, such as interactions between sales representatives with healthcare providers, has the potential to counter-act these important public health initiatives and to put our employees and people in doctors' offices at unnecessary risk.

Accordingly, as Amarin is intently focused on improving public health by reducing cardiovascular risk, currently the most damaging disease in the industrialized world, and consistent with our corporate values, we have announced immediate suspension of field based face-to-face interactions for the next two weeks, until Monday, March 30th. To directly support patient care, Amarin plans to continue to provide digital and internet-based educational materials and copay cards and will continue to ship samples. It is too early for the company to assess the impact of the COVID-19 pandemic and these actions on Amarin's revenue growth and previously reported revenue guidance. Such actions follow reports in early March of record prescription levels, and record new prescription levels, for VASCEPA® (icosapent ethyl). We understand that other pharmaceutical companies are taking similar actions. We will continue during this period with non-personal promotion initiatives and use some of the time for further training of our field personnel. We will continue to monitor the situation and provide updates at an appropriate time.

"As a company focused for more than a decade on fighting cardiovascular disease, which in the United States alone results in one stroke, heart attack or death every 14 seconds, we are determined to do our part to protect public health and the health of our many valued employees," said John Thero, president and chief executive officer of Amarin. "We have developed a roadmap of remote working activities for us to continue to help many patients with persistent cardiovascular risk, including using virtual customer tools to maintain contact and enhanced sales training. Our efforts are designed to do our part to help reduce the spread of COVID-19, protect the health of our employees and their families and preserve healthcare resources at a critical interim period for those most in need and, ultimately, to save lives. We applaud the dedication and efforts of healthcare professionals internationally as they prioritize their own efforts to address the public health crisis presented by COVID-19. And, we express our condolences to everyone who is suffering from this pandemic. We will work to continue our diligent efforts to bring to healthcare professionals and the public our contribution to improved treatment of cardiovascular risk, which is not only an enormous and growing medical issue worldwide but also a leading factor of increased risk to those infected by COVID-19."

In addition, the company responded to questions regarding whether its supply chain for Vascepa is likely to be significantly impacted by COVID-19. Amarin's supply chain is diversified and therefore mitigates geographical risks. None of Amarin's manufacturing is conducted in China. Furthermore, Amarin has built significant stockpiles of VASCEPA in the United States. VASCEPA is reported to be available in pharmacies throughout the United States and similarly available in other countries where it is approved for sale. From the information that is currently available, Amarin does not believe coronavirus will have a major impact, if any impact, on its ability to supply VASCEPA to support its growing business.

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 Disease

Cardiovascular disease is an enormous and growing medical issue worldwide.[4, 5] In the United States alone, a heart attack, stroke, death or other major cardiovascular event is experienced every 14 seconds.[6]

Controlling bad cholesterol, also known as LDL-C, is one way to reduce a patient's risk of experiencing a cardiovascular event. However, even with the achievement of target LDL-C levels, millions of patients still have significant and persistent cardiovascular risk, especially those patients with high triglycerides. Statin therapy has been shown to control LDL-C, thereby reducing the risk of cardiovascular events by 25-35% – but that still leaves 65-75% of risk remaining.[7] People with high triglycerides have 35% more cardiovascular events compared to people with normal (in range) triglycerides taking statins.[8,9,10]

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.

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

  º established cardiovascular disease or

  º 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 for bleeding should be monitored.

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 Amarin efforts to stem the COVID-19 virus and cardiovascular disease, efforts to continue to help patients with persistent cardiovascular risk, such as through virtual customer tools to maintain contact and enhanced sales training and Amarin's current believe about the impact of COVID-19 on its ability to supply VASCEPA to support its growing business. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. As circumstances change, the proactive steps taken by Amarin may be extended and it current outlook may change. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: uncertainties associated generally with the commercial success of pharmaceutical products such as VASCEPA, reliance on third parties in the VASCEPA supply chain and uncertainties related to virus containment efforts worldwide. In addition, Amarin's ability to effectively commercialize VASCEPA will depend in part on its ability to continue to effectively finance its business, efforts of third parties, its ability to create market demand for VASCEPA through education, marketing and sales activities, to achieve 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 maintain exclusivity through patent protection and to comply with legal and regulatory requirements in connection with the sale and promotion of VASCEPA. 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 annual report on Form 10-K. 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.

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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