Amarin Corporation

Amarin Comments on Ruling in VASCEPA® ANDA Litigation

March 30, 2020

DUBLIN, Ireland and BRIDGEWATER, N.J., March 30, 2020 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) today commented on the United States District Court for the District of Nevada's ruling in favor of the generic companies in the company's patent litigation against two filers of abbreviated new drug applications, or ANDAs, for Amarin's VASCEPA® (icosapent ethyl) capsule franchise. Based on Amarin's review of U.S. Food and Drug Administration's (FDA's) website, an ANDA for VASCEPA has not been approved, which would be required for launch of a generic product in the United States. The company thus does not believe there is an impending generic launch by the litigants that would compete with VASCEPA at this time.

"Amarin strongly disagrees with the ruling and will vigorously pursue all available remedies, including an appeal of the Court's decision and a preliminary injunction pending appeal to, if an ANDA is approved by FDA, prevent launch of generic versions of VASCEPA in the United States," said John F. Thero, president and chief executive officer of Amarin. "At Amarin, we have a strong balance sheet with capacity and flexibility, and we plan to fight to protect our VASCEPA franchise for the benefit of our patients, physicians, the broader healthcare community and our investors. We believe we are favorably situated to obtain an injunction against generic launch pending appeal, subject to our posting a bond to secure generics' lost profits in the event that generics prevail on appeal. As we work to take all legal actions necessary to defend and protect our intellectual property, we will continue to press forward with our educational and promotional efforts for VASCEPA in treating indicated patients at high risk of cardiovascular events, such as heart attack and stroke. After we determine the outcome of our effort to prevent a generic launch (if an ANDA approval is obtained), we expect to provide an update on how we would adjust certain promotional activities for VASCEPA in the United States."

Geographies outside the United States in which VASCEPA is sold and under regulatory review are not subject to this litigation and judgment. No generic litigation is pending outside the United States. VASCEPA remains available by prescription in Canada, Lebanon and the United Arab Emirates. In Canada, VASCEPA has the benefit of eight years of data protection afforded through Health Canada (until the end of 2027), in addition to separate patent protection with expiration dates that could extend into 2039. Amarin, together with its commercial partners in select geographies, is pursuing additional regulatory approvals for VASCEPA in the European Union, China and the Middle East. Ten to eleven years of market protection is anticipated due to regulatory exclusivity in the European Union subject to pending VASCEPA approval expected later this year, in addition to pending patent protection that could extend into 2033.

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.[1,2] In the United States alone, a heart attack, stroke, death or other major cardiovascular event is experienced every 14 seconds.[3]

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.[4] People with high triglycerides have 35% more cardiovascular events compared to people with normal (in range) triglycerides taking statins.[5,6,7]

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
  - ° 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 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 expectations regarding plans for appeal, to obtain an injunction against generic launch pending appeal, subject to our posting a bond to secure generics' lost profits in the event that generics prevail on appeal, to update on the degree to which we would scale back certain promotional activities for VASCEPA in the United States, to otherwise seek to maintain exclusivity for

VASCEPA in the United States and elsewhere based on, as applicable, litigation, regulatory exclusivity and issued and allowed patents and the expected expiration dates of those patent applications and issued patents to correspond with associated exclusivity protection and plans to continue commercialization efforts in the United States. There can be no guarantee we would be successful in any of such efforts. 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 the commercial success of pharmaceutical products such as VASCEPA; the risk of loss in the planned appeal of the Court's judgment and in seeking preliminary injunction; that patent applications may not result in issued patents, and that issued patents may not prevent competitors from competing with VASCEPA; the risk that new competitors may further challenge the exclusivity afforded by the same patents at issue in this litigation through a new litigation or otherwise seek to gain marketing approval for generic versions of VASCEPA or branded competitive products based on new clinical studies; and the risk that trade secrets may not be maintained and that other circumstances that create barriers to competition with VASCEPA may not last. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. 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, 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.

Amarin Contact Information

Investor and Media Inquiries:
Elisabeth Schwartz
Investor Relations
Amarin Corporation plc
In U.S.: +1 (908) 719-1315
investor.relations@amarincorp.com (investor inquiries)
PR@amarincorp.com (media inquiries)

Lee M. Stern
Solebury Trout
In U.S.: +1 (646) 378-2992
lstern@soleburytrout.com

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