Amarin Corporation

Amarin Honored by BioNJ with Innovator Award for VASCEPA® Development and Regulatory Approval

February 7, 2020

DUBLIN, Ireland and BRIDGEWATER, N.J., Feb. 06, 2020 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), announced today that BioNJ awarded Amarin with an Innovator Award in recognition of the approval of a new indication for VASCEPA® (icosapent ethyl) by the U.S. Food and Drug Administration (FDA) in December 2019. This approval positions VASCEPA as the first and only drug approved to reduce cardiovascular events in millions of select high-risk patients. The approval follows over a decade of research and development in a clinically challenging disease area characterized by significant unmet medical need.

“Amarin is proud to be part of BioNJ’s business community,” stated Steven Ketchum, PhD, Amarin’s president of R&D and chief scientific officer, who accepted the award on Amarin’s behalf. “New Jersey’s biotech hub has enabled Amarin to hire world-class talent for its Bridgewater location. Through the skills and dedicated efforts of such talented people, we have pioneered an important, practice-changing therapy, VASCEPA, which we believe will help millions of people avoid adverse cardiovascular events. We are confident the region’s pool of talented professionals will continue to be a valuable resource in our continued expansion.”

“BioNJ is happy to present Amarin with the Innovator Award for its dedication to expanding this affordable and innovative therapy, VASCEPA, for use to reduce cardiovascular risk,” said Debbie Hart, president and chief executive officer of BioNJ. “Amarin has clearly demonstrated that it is a committed corporate citizen and is dedicated to the continued expansion of the biotech industry in the State of New Jersey.”

The success of VASCEPA as a recognized new, cost-effective therapy to reduce cardiovascular risk has propelled Amarin’s growth from a dozen employees in 2011 to its current size of over 1000 people in the United States and Ireland, over 100 of whom are in New Jersey.

Amarin’s successful completion of the landmark REDUCE-IT® clinical trial was the basis for FDA-approval of VASCEPA in its important new cardiovascular risk reduction indication. In this study of patients on statin therapy who, despite well-controlled cholesterol had various cardiovascular risk factors, VASCEPA demonstrated a robust 25% reduction in major adverse cardiovascular events beyond the benefits of existing standard of medical care. In recognition of these unprecedented results, VASCEPA received a 16-0 vote in favor of approval by the FDA Endocrinologic and Metabolic Drugs Advisory Committee, with subsequent approval granted by the FDA. VASCEPA has been recognized by eight major medical societies on four continents as a new standard of medical care for treatment of studied high-risk patients. VASCEPA is a prescription medicine used along with statins to reduce the risk of heart attack, stroke and certain types of heart issues requiring hospitalization in adults with elevated (≥ 150 mg/dL) triglyceride levels and heart (cardiovascular) disease, or diabetes and 2 or more additional risk factors for heart disease.

Cardiovascular disease (CVD) is the leading cause of death in the United States, resulting in one heart attack, stroke or death every 14 seconds.[1] Nearly half of the entire US population, 121.5 million adults, have some form of heart disease.[2] The U.S. spends approximately $555 billion in direct (medical) and indirect costs on CVD each year. By 2035, 45.1% of the US population is projected to have some form of CVD. Total costs of CVD are expected to reach $1.1 trillion in 2035, with direct medical costs projected to reach $748.7 billion and indirect costs estimated to reach $368 billion.[1]

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 BioNJ

BioNJ is the life sciences trade association for New Jersey with nearly 400 Member companies representing research-based life sciences organizations and stakeholders across the ecosystem from the largest biopharmaceutical companies to early stage start-ups. BioNJ is dedicated to ensuring a vibrant ecosystem where Science is Supported, Companies are Created, Drugs are Developed and Patients are Paramount. Because Patients Can’t Wait®, BioNJ supports its Members in the discovery, development and commercialization of therapies and cures that save and improve lives and lessen the burden of illness and disease to society by driving capital formation, fostering entrepreneurship, advocating for public policies that advance medical innovation, providing access to talent and education and offering a cost-saving array of critical commercial resources. For more information about BioNJ, please visit www.BioNJ.org

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 VASCEPA use and Amarin's belief that the drug could help millions of people avoid adverse cardiovascular events and statements about plans for company expansion. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. 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 comply with legal and regulatory requirements in connection with the sale and promotion of VASCEPA and to maintain patent protection for VASCEPA. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: 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 not be determined to be infringed or upheld in patent litigation and applications may not result in issued patents sufficient to protect the VASCEPA franchise. 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.

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

References

[1] Heart Disease and Stroke Statistics — 2020 Update: A Report From the American Heart Association
[2] 2020 Heart Disease and Stroke Statistical Update Fact Sheet At-a-Glance