Amarin Commences Commercial Initiatives for VAZKEPA in European Union Following Recent Regulatory Approval for Cardiovascular Risk Reduction Indication

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Reimbursement dossiers for first 10 countries to be filed in coming months

150 people hired and on-track to be deployed by mid-Q2 2021 supplemented by digital outreach and medical education programs with initial top priority on Germany

VAZKEPA commercial launch in Germany planned for Q3 2021

DUBLIN, Ireland and BRIDGEWATER, N.J., April 06, 2021 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ: AMRN) today provided updates regarding its plans for the commercial launch of VAZKEPA (icosapent ethyl) in Europe following the March 30, 2021 announcement of receipt of market authorization from the European Commission (EC). VAZKEPA is the first EC-approved product to be marketed and sold for cardiovascular risk reduction in high-risk, statin-treated adult patients who have elevated triglycerides (≥150 mg/dL) and other risk characteristics as studied in REDUCE-IT®.

Following this approval, Amarin commenced training sales representatives in Germany to advance pre-launch disease and brand awareness initiatives in preparation for the planned commercial launch of VAZKEPA in Germany before the end of Q3 2021. The company expects to have approximately 150 sales representatives deployed for pre-launch product and disease state awareness programs by mid-Q2 2021.

"We have hired talented and experienced pharmaceutical sales and marketing professionals for our European commercial team and are activating steps to increase product and market need awareness, while advancing our market access negotiations," said Karim Mikhail, senior vice president, commercial head Europe of Amarin. "We are taking a thoughtful and proactive approach to leveraging the vast global experience of our team, while incorporating the learnings from other product launches made during the COVID-19 era. We are highly motivated to effectively launch VAZKEPA in Europe as it offers an exciting opportunity to help patients at risk of cardiovascular events. VAZKEPA is a safe and effective new product that benefits from more than a decade of worldwide clinical development and testing that support its use to significantly reduce cardiovascular events."

Use of icosapent ethyl is now recommended by 15 medical societies for cardiovascular risk reduction reflecting that the data supporting the effectiveness of VAZKEPA is robust, the medical need is high and key opinion leaders in these medical societies agree this important new drug should be used to improve patient care. As VAZKEPA was just recently authorized in Europe as a new drug (new active substance), and there is no other product approved in Europe for VAZKEPA's indication, current awareness of VAZKEPA in Europe among healthcare professionals at-large is relatively low.

Amarin believes that increasing awareness of VAZKEPA in Germany and illuminating the patient population that can benefit from this new drug are important to VAZKEPA's early launch success. Prior to VAZKEPA's recent approval, as is typical for any new drug, branded market education regarding VAZKEPA was prohibited in Europe. Consequently, immediately following VAZKEPA's approval in the European Union the company has initiated its educational and promotional plans to underscore the significant residual cardiovascular risk for the patient population indicated for VAZKEPA and to introduce to healthcare professionals the value VAZKEPA has demonstrated in lowering such risk.

Starting in the second quarter 2021, outreach by Amarin's field force in Germany will be supplemented by various forms of market education, including digital outreach and omnichannel engagement for key stakeholders. Amarin's planned educational initiatives are intended to increase awareness among cardiologists, diabetologists, and general practitioners. In addition, based on the differentiated safety and efficacy profile of this unique drug for its approved label and the growing global data in support of its pharmacoeconomic benefits, our planned educational efforts will also be aimed at regional payers.

As is typical of drug launches in Europe, following approval and prior to launch, market access (reimbursement) needs to be secured on a country-by-country basis and product awareness of VAZKEPA needs to increase in each country[1]. In seeking market access, the company expects to file dossiers in ten (10) European countries in the coming months, including the largest countries of Europe. Each of these dossiers have already undergone months of preparation and include the data demonstrating the uniqueness of VAZKEPA from a scientific perspective, various country-specific demographic data sets to define the eligible patient population based on the label, and finally proposed pricing. Amarin is seeking pricing that it believes is well justified based on the demonstrated effectiveness of VAZKEPA and the high cost to society of heart attacks, strokes and other cardiovascular events that VAZKEPA can help avoid while also reducing pain and suffering for at-risk patients and their families. After the first wave of 10 country submissions in Europe, Amarin intends to pursue a second wave of European reimbursement dossiers in its efforts to bring VAZKEPA to all patients who can benefit from it.

Amarin anticipates direct access to healthcare professionals and at-risk patients will remain constrained while COVID-19 persists. Learning from the experience of other drugs launched during the COVID-19 pandemic, part of the planned multi-faceted educational programs in Europe will include increased awareness of the unique effects of VAZKEPA. For example, key elements of the planned education initiatives are expected to focus on increasing the scientific awareness of the importance of measuring and using triglyceride (TG) levels as an identifier of cardiovascular risk, noting that VAZKEPA's cardiovascular risk reduction effects extend beyond TG lowering and are believed to be multifactorial, including anti-inflammatory and antiplatelet effects. While many people are speculating that the impact of COVID-19 will gradually abate around the planned commercial launch of VAZKEPA in Germany in Q3 2021, digital outreach, and other forms of educating healthcare professionals will be emphasized to support the work of the sales professionals being deployed. In order to advance pre-launch market awareness of VAZKEPA, to allow time for the impact of COVID-19 to recede and to avoid the challenges of launching prior to the summer holiday period when access to healthcare professionals can be more difficult, it is likely that the launch in Germany will be the latter half of Q3. Launch timing will be further refined after feedback is received from the company's early branded awareness and education initiatives.

Amarin is giving initial priority to launching VAZKEPA in Germany while making plans for commercialization in countries throughout Europe. Staffing in other European countries, and launch timing in these other countries, will depend on progress in gaining market access on a country-by-country basis.

Previously Amarin had provided guidance that its European staffing at the end of 2021 would be approximately 200 people. Based on the company's current plans and expectations, Amarin now expects to grow its staffing in Europe to approximately 300 people by the end of 2021, with further increases planned as market access is expanded in various countries. This increase in expected staffing reflects the breadth of the EC-approved label for VAZKEPA, positive initial feedback Amarin is receiving from European scientific leaders, and optimism that the impact of COVID-19 will recede during the second half of 2021.

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 REDUCE-IT®
REDUCE-IT was a global cardiovascular outcomes study designed to evaluate the effect of VASCEPA in adult patients with LDL-C controlled to between 41-100 mg/dL (median baseline 75 mg/dL) by statin therapy and various cardiovascular risk factors including persistent elevated triglycerides between 135-499 mg/dL (median baseline 216 mg/dL) and either established cardiovascular disease (secondary prevention cohort) or diabetes mellitus and at least one other cardiovascular risk factor (primary prevention cohort).

REDUCE-IT, conducted over seven years and completed in 2018, followed 8,179 patients at over 400 clinical sites in 11 countries with the largest number of sites located within the United States. REDUCE-IT was conducted based on a special protocol assessment agreement with FDA. The design of the REDUCE-IT study was published in March 2017 in *Clinical Cardiology.*[2] The primary results of REDUCE-IT were published in *The New England Journal of Medicine* in November 2018.[3] The total events results of REDUCE-IT were published in the *Journal of the American College of Cardiology* in March 2019.[4] These and other publications can be found in the R&D section on the company's website at www.amarincorp.com.

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, 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.

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 U.S. FDA-APPROVED VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT WWW.VASCEPA.COM.

Forward-Looking Statements

This press release contains forward-looking statements, including statements about the timing of promotional and educational initiatives, the timing of market access initiatives and the potential of VAZKEPA (known as VASCEPA in the United States) to favorably affect cardiovascular risk in appropriate patients, to make a difference in the lives of the many millions of patients throughout Europe who are at risk of a cardiovascular event, with respect to Amarin being well-positioned for a successful European launch and related to the potential for extended patent protection. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties that may individually or together impact the matters herein and cause actual results, events and performance to differ materially from such forward-looking statements. Among the factors that could cause actual results to differ materially from those described or projected herein include the following: events that could impact

future regulatory assessment by the European Commission, such as delays due to COVID-19 restrictions, later arising data, regulatory reviews and pricing assessments, and the successful implementation of commercialization plans or other information, events that could interfere with the grant or issuance of a patent, continued validity or enforceability of a patent; uncertainties associated with litigation generally and patent litigation specifically; Amarin's ability generally to maintain adequate patent protection and successfully enforce patent claims against third parties; and uncertainties associated generally with research and development and regulatory submissions, reviews, action dates and approvals. 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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[1] For more information see the FAQ titled, *What are Amarin's plans and timing for VAZKEPA initial commercial launch in Europe?*, in the investor relations section of the Amarin corporate website at https://investor.amarincorp.com/.

[2] Bhatt DL, Steg PG, Brinton E, et al., on behalf of the REDUCE-IT Investigators. Rationale and Design of REDUCE-IT: Reduction of Cardiovascular Events with Icosapent Ethyl–Intervention Trial. *Clin Cardiol*. 2017;40:138-148.

[3] Bhatt DL, Steg PG, Miller M, et al. Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglyceridemia. *N Engl J Med.* 2019;380(1):11-22.

[4] Bhatt DL, Steg PG, Miller M, et al., on behalf of the REDUCE-IT Investigators. Reduction in first and total ischemic events with icosapent ethyl across baseline triglyceride tertiles. *J Am Coll Cardiol*. 2019;74:1159-1161.