Amarin Corporation

Amarin Provides Mid-2019 Update, Including Commercialization Plans for Vascepa® and Updates Full Year 2019 Revenue Guidance

July 2, 2019

- ***Record Revenue Achieved in 1H19 Primarily Due to Increased Demand for Vascepa***
- ***Guidance for Total 2019 Revenue Increased to a Range of $380 to $420 Million from $350 Million Following Unaudited Second Quarter Results Estimated Between $97 and $101 Million, or Between $170 and $174 Million for the First Half of 2019***
- ***U.S. Sales Force to Double in Size; Recruiting Commenced***
- ***Vascepa sNDA PDUFA Goal Date On-Track for September 28, 2019; Potential for Therapy to Become First Prescription Product Available for Cardiovascular Risk Reduction in Patients with Elevated Triglyceride Levels, Despite Statin Therapy***

BEDMINSTER, N.J. and DUBLIN, Ireland, July 02, 2019 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), a pharmaceutical company focused on improving cardiovascular health, today provided a business update, including that the company is increasing revenue guidance for 2019 and planning to further increase its commercial expansion efforts to align with its progress and outlook that the realizable opportunity for *Vascepa*® (icosapent ethyl) is larger than previously believed. These revised plans follow estimated record revenues for the quarter ended June 30, 2019 and assume expanded FDA labelling for *Vascepa*.

sNDA Update

As previously announced, Amarin submitted an sNDA to the U.S. Food and Drug Administration (FDA) on March 28, 2019, seeking to expand the indication for *Vascepa*. The sNDA was based on the positive results of the landmark REDUCE-IT™ cardiovascular outcomes study. If approved, the expanded label is expected to allow for considerably broader promotion of *Vascepa* in the United States. As announced in May 2019, the FDA accepted the sNDA for filing and granted Priority Review designation with an assigned PDUFA goal date of September 28, 2019.

The FDA grants Priority Review designation to applications for drugs that, if approved, have the potential to offer significant improvements in the effectiveness and safety of the treatment of serious conditions when compared to standard applications. Assuming the FDA approves this sNDA, *Vascepa* is anticipated to be the first drug with an indication to reduce residual cardiovascular risk in patients with statin-managed LDL-cholesterol, but persistent elevated triglyceride (TG) levels, an important indicator of cardiovascular disease.

The results of the REDUCE-IT study were published in *The New England Journal of Medicine* in November 2018.[1] Additional results and analysis of total recurrent events observed in REDUCE-IT were published in the *Journal of American College of Cardiology* in March 2019.[2]

Vascepa is currently indicated as an adjunct to diet to reduce TG levels in adults with severe (TG ≥500 mg/dL) hypertriglyceridemia, an important but much smaller patient population than can be addressed with an approval of this sNDA.

To date, the FDA has not informed Amarin as to whether it plans to convene an Advisory Committee meeting (AdCom) to review the sNDA. As previously disclosed, Amarin continues to prepare in the event that an AdCom is convened. If Amarin is informed definitively that there will or will not be an AdCom, the company plans to update investors accordingly.

Preliminary (Unaudited) First Half 2019 Financial Results

Record Revenue Levels Achieved: Net total revenue for the three and six months ended June 30, 2019 are estimated to have reached between $97 and $101 million and between $170 and $174 million, respectively. Both the second quarter and first half of 2019 results represent record revenue levels for Amarin. These results, which are subject to auditor review, represent an increase of approximately $44 to $48 million (approximately 84% to 92%) for the second quarter of 2019 over the corresponding period of 2018 and an increase of approximately $73 to $77 million (approximately 76% to 80%) for the first half of 2019 over the corresponding period of 2018. These results consist predominantly of U.S. sales-driven increases in prescriptions for *Vascepa*. Wholesaler inventory levels of *Vascepa* were within normal industry ranges at the end June 2019.

Current Assets: Amarin ended June 2019 with cash and cash equivalents of approximately $221 million (compared to $211 million at March 31, 2019), approximately $94 million in net accounts receivable and approximately $47 million in inventory.

No Debt, Except Remaining Balance of Royalty Bearing Instrument: Amarin ended June 2019 with no debt except the remaining balance on its royalty bearing instrument which is repaid at a rate of 10% of *Vascepa* revenues; aggregate repayment of less than $74 million remains until this royalty-like obligation is fully extinguished.

2019 Financial and Operational Guidance

Amarin initially provided guidance for 2019 in its press release dated January 4, 2019. Amarin now makes the following updates to that guidance:

2019 Revenue Guidance: Forecasting *Vascepa* revenue levels at this early stage remains difficult. Based on estimated total revenue results for the first half of 2019 which exceeded prior expectations, Amarin increases its guidance for 2019 net total revenue to a range of $380 to $420 million. While Amarin remains optimistic that *Vascepa* will generate billions of dollars in revenue in the years to come, the history of other therapies for chronic conditions suggests that growth builds over multiple years, and thus, the company is not prepared to provide quantified guidance regarding revenue levels beyond 2019.

Commercial Expansion in United States: Amarin has accelerated and further expanded its commercialization plans for *Vascepa* in the United States. Amarin intends to increase the size of its U.S. sales force to approximately 800 sales representatives with the aim of having its expanded team hired, trained and deployed by October 2019. This increase would represent a doubling of the size of Amarin's current sales force.

The timing of such expansion had been accelerated in part due to the priority review designation of the sNDA for *Vascepa.* Assuming label expansion for *Vascepa* on the September 28, 2019 PDUFA date, Amarin expects to have educational and promotional materials available by early October 2019 to promote *Vascepa* based on the new label.

The size of the planned expansion reflects the result of evaluations involving multiple contributing factors. Previously Amarin had estimated the potential expansion of its sales force to reach between 600 and 800 sales representatives and for the expansion to potentially occur in phases. The decision to expand the sales force to approximately 800 sales representatives by October 2019 was based on new information including the encouraging progress being made by sales representatives hired at the start of 2019, positive feedback from physicians with deep understanding of the REDUCE-IT data, additional data on the commercial opportunity that exists in detailing physicians who have not yet been educated about *Vascepa* and data suggesting that education of healthcare professionals regarding *Vascepa* will be improved if our sales representatives call on physicians with greater frequency.

As a reminder, in late 2018, Amarin hired, trained and deployed 265 new and qualified sales representatives within approximately three months after learning the results of REDUCE-IT. At the time, more than 20,000 applications were received for the 265 open sales positions. Based on this track record and the robust results of *Vascepa* clinical trials, Amarin is confident it can double its sales force to 800 sales representatives by October 2019.

While Amarin is confident that expanding its sales force will result in meaningful revenue growth beyond 2019, the company's revenue guidance for 2019 as described above anticipates little incremental contribution in 2019 from these newly hired sales representatives. Based on available data, it typically requires multiple months for newly hired sales representatives to become meaningfully productive particularly if they are calling on healthcare professionals who also are new to *Vascepa*, which will be the case for a large part of such sales force expansion.

Amarin intends to support its expanded U.S. sales team with multiple promotional and educational programs. All such initiatives will be aimed at providing truthful and non-misleading information to lead to improved patient care. Included in Amarin's promotion plans is a direct-to-consumer advertising campaign, subject to review by the FDA's Office of Prescription Drug Promotion (OPDP). The company anticipates submitting proposed *Vascepa* advertisements to OPDP in October 2019. Based on the timeline for other companies getting consumer advertising reviewed by FDA following new labelling, assuming new *Vascepa* labelling, launch of such branded advertising is anticipated in the second quarter of 2020.

Plans for commercialization of *Vascepa* outside of the United States remain unchanged, including intentions to submit for regulatory approval of *Vascepa* in the European Union near the end of 2019.

Comment from Amarin's President and CEO

"We are pleased with the progress made to date, including the significant revenue growth we've achieved for *Vascepa*," commented John Thero, president and chief executive officer of Amarin. "We anticipate *Vascepa* revenue growth to accelerate further after label expansion approval and with a larger sales team, and then again after we commence promotion of *Vascepa* for cardiovascular risk reduction on television and through other media. We are preparing for a robust launch of REDUCE-IT data with the aim of helping physicians improve patient care for millions of patients with residual cardiovascular risk after their cholesterol is controlled, as identified by elevated triglycerides."

About Amarin

Amarin Corporation plc. is a rapidly growing, innovative pharmaceutical company focused on developing therapeutics to improve cardiovascular health. Amarin's product development program leverages its extensive experience in polyunsaturated fatty acids and lipid science. *Vascepa* (icosapent ethyl) is Amarin's first FDA-approved drug and is available by prescription in the United States, Lebanon and the United Arab Emirates. Amarin's commercial partners are pursuing additional regulatory approvals for *Vascepa* in Canada, China and the Middle East. For more information about Amarin, visit www.amarincorp.com.

About REDUCE-IT™

REDUCE-IT[1] was an 8,179-patient multinational cardiovascular outcomes study completed in 2018. REDUCE-IT evaluated the effect of prescription pure EPA therapy as an add-on to statins in patients with high cardiovascular risk who, despite stable statin therapy, had elevated triglyceride levels (at least 135 mg/dL). A large portion of the male and female patients enrolled in this outcomes study were diagnosed with type 2 diabetes.

More information on the REDUCE-IT study results can be found at www.amarincorp.com.

About Cardiovascular Disease

Worldwide, cardiovascular disease (CVD) remains the #1 killer of men and women. In the United States CVD leads to one in every three deaths – one death approximately every 38 seconds – with annual treatment cost in excess of $500 billion.[3, 4]

Multiple primary and secondary prevention trials have shown a significant reduction of 25% to 35% in the risk of cardiovascular events with statin therapy, leaving significant persistent residual risk despite the achievement of target LDL-C levels.[5]

Beyond the cardiovascular risk associated with LDL-C, genetic, epidemiologic, clinical and real-world data suggest that patients with elevated triglycerides (TG) (fats in the blood), and TG-rich lipoproteins, are at increased risk for cardiovascular disease.[6-9]

About *Vascepa*® (icosapent ethyl) Capsules

Vascepa (icosapent ethyl) capsules are a single-molecule prescription product consisting of the omega-3 acid commonly known as EPA in ethyl-ester form. *Vascepa* is not fish oil, but is derived from fish through a stringent and complex FDA-regulated manufacturing process designed to effectively eliminate impurities and isolate and protect the single molecule active ingredient from degradation. *Vascepa*, known in scientific literature as AMR101, has been designated a new chemical entity by the FDA. Amarin has been issued multiple patents internationally based on the unique clinical profile

of *Vascepa*, including the drug's ability to lower triglyceride levels in relevant patient populations without raising LDL-cholesterol levels.

Indication and Usage Based on Current FDA-Approved Label (not including REDUCE-IT results)

- *Vascepa* (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia.
- The effect of *Vascepa* on the risk for pancreatitis and cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined.

Important Safety Information for *Vascepa* Based on Current FDA-Approved Label (not including REDUCE-IT results) (Includes Data from Two 12-Week Studies (n=622) (MARINE and ANCHOR) of Patients with Triglycerides Values of 200 to 2000 mg/dL)

- *Vascepa* is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to *Vascepa* or any of its components.
- In patients with hepatic impairment, monitor ALT and AST levels periodically during therapy.
- Use with caution in patients with known hypersensitivity to fish and/or shellfish.
- The most common reported adverse reaction (incidence >2% and greater than placebo) was arthralgia (2.3% for *Vascepa*, 1.0% for placebo). There was no reported adverse reaction >3% and greater than placebo.
- Adverse events and product complaints may be reported by calling 1-855-*VASCEPA* or the FDA at 1-800-FDA-1088.
- Patients receiving treatment with *Vascepa* and other drugs affecting coagulation (e.g., anti-platelet agents) should be monitored periodically.
- Patients should be advised to swallow *Vascepa* capsules whole; not to break open, crush, dissolve, or chew *Vascepa*.

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

Important Safety Information for *Vascepa* based on REDUCE-IT, as previously reported in The New England Journal of Medicine[1] publication of the primary results of the REDUCE-IT study:

- Excluding the major adverse cardiovascular events (MACE) results described above, overall adverse event rates in REDUCE-IT were similar across the statin plus *Vascepa* and the statin plus placebo treatment groups.
- There were no significant differences between treatments in the overall rate of treatment emergent adverse events or serious adverse events leading to withdrawal of study drug.
- There was no serious adverse event (SAE) occurring at a frequency of >2% which occurred at a numerically higher rate in the statin plus *Vascepa* treatment group than in the statin plus placebo treatment group.
- Adverse events (AEs) occurring in 5% or greater of patients and more frequently with *Vascepa* than placebo were:
  – peripheral edema (6.5% *Vascepa* patients versus 5.0% placebo patients), although there was no increase in the rate of heart failure in *Vascepa* patients
  – constipation (5.4% *Vascepa* patients versus 3.6% placebo patients), although mineral oil, as used as placebo, is known to lower constipation, and
  – atrial fibrillation (5.3% *Vascepa* patients versus 3.9% placebo patients), although there were reductions in rates of cardiac arrest, sudden death and myocardial infarctions observed in *Vascepa* patients
- There were numerically more SAEs related to bleeding in the statin plus *Vascepa* treatment group although overall rates were low with no fatal bleeding observed in either group and no significant difference in adjudicated hemorrhagic stroke or serious central nervous system or gastrointestinal bleeding events between treatments.
- In summary, *Vascepa* was well tolerated with a safety profile generally consistent with clinical experience associated with omega-3 fatty acids and current FDA-approved labeling of such products.

Vascepa has been approved for use by the United States Food and Drug Administration (FDA) as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. FDA has not reviewed and opined on a supplemental new drug application related to REDUCE-IT. FDA has not reviewed the information herein or determined whether to approve *Vascepa* for use to reduce the risk of MACE. Nothing in this press release should be construed as promoting the use of *Vascepa* in any indication that has not been approved by the FDA.

Important Cautionary Information About These Data

Further REDUCE-IT data assessment and data release could yield additional useful information to inform greater understanding of the trial outcome. For example, detailed data assessment by regulatory authorities, such as the FDA and Health Canada, will continue and take several months to complete and announce. The final evaluation by regulatory authorities of the totality of efficacy and safety data from REDUCE-IT may include some or all of the following, as well as other considerations: new information or analyses affecting the degree of treatment benefit on studied endpoints; study conduct and data robustness, quality, integrity and consistency; additional safety data considerations and risk/benefit considerations; and consideration of REDUCE-IT results in the context of other clinical studies. Because regulatory reviews are typically fluid and not definitive interactions between sponsor and agency on individual elements of an application and related information, Amarin does not plan to update investors on ongoing communications with regulatory authorities. Amarin plans to announce the final outcome of such regulatory reviews when appropriate.

Recurrent event analyses for the total primary endpoint events and for the total key secondary endpoint in REDUCE-IT as published in the Journal of the American College of Cardiology were conducted using a series of statistical models. These analyses were tertiary or exploratory endpoints; most of the models used were prespecified and one was post hoc. Each recurrent event statistical model has inherent strengths and weaknesses, with no single model considered definitive or outperforming the other models, and this is an evolving field of science. Nonetheless, results from the total

primary and total key secondary endpoint events analyses are consistent across the various recurrent event statistical models and are also consistent with the original primary and secondary endpoint results. Together, the REDUCE-IT recurrent event analyses and the original primary and key secondary endpoint analyses support the robustness of the clinical benefit of *Vascepa* therapy in reducing cardiovascular risk.

Forward-Looking Statements

This press release contains forward-looking statements, including expectations regarding revenue and prescription growth, including updated revenue guidance for 2019; sales force expansion and marketing initiatives expected in 2019 and beyond; FDA regulatory review, including the timing and outcome of such review; the applicability and reliability of REDUCE-IT results; and the expected outcome and timing of review elements and market dynamics for *Vascepa*. 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 gain regulatory approvals, 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 reviews and approvals; the risk that sales may not meet expectations and related cost may increase beyond expectations; the risk that patents may not be 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.

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