

# Amarin Corporation

## Amarin Schedules Webcast Discussion of Primary REDUCE-IT™ Trial Results Following Presentation at 2018 Scientific Sessions of American Heart Association

October 26, 2018

### Webcast to Commence at 7:15 p.m. CT / 8:15 p.m. ET, Saturday, November 10, 2018

BEDMINSTER, N.J. and DUBLIN, Ireland, Oct. 26, 2018 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), a pharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health, looks forward to the presentation of primary results of Amarin's landmark cardiovascular outcomes study of Vascepa® (icosapent ethyl), the REDUCE-IT™ study, as a late-breaker at the 2018 Scientific Sessions of American Heart Association (AHA) on November 10, 2018 in Chicago, Illinois, as previously disclosed. Amarin expects the following activities at AHA will be of most interest to Amarin investors:

1. Presentation of REDUCE-IT clinical trial results: Saturday, Nov. 10, 2018 at 2:18 p.m. Central Time (CT) / 3:18 p.m. Eastern Time (ET)
2. Amarin investor/analyst conference call to discuss REDUCE-IT results: Saturday, Nov. 10, 2018 at 7:15 p.m. CT / 8:15 p.m. ET
3. Continuing medical education programs with REDUCE-IT on the agenda (the curriculum of which is developed independently of Amarin): Sunday, Nov. 11, 2018 at 6:30 p.m. CT / 7:30 p.m. ET and Monday, Nov. 12, 2018 at 6:00 a.m. CT / 7:00 a.m. ET

#### Presentation of REDUCE-IT Clinical Results

Presentation of REDUCE-IT primary clinical trial results is classified by the AHA as late-breaking clinical trial results and listed as Main Event 1 for timeframe described above. A link to the notice of this presentation is provided at:

<http://www.abstractsonline.com/pp8/#!/4682/presentation/59402>.

The AHA makes available a live stream and archived webcast of the REDUCE-IT primary clinical trial results presentation at:

[https://professional.heart.org/professional/EducationMeetings/MeetingsLiveCME/ScientificSessions/UCM\\_488605\\_Sessions-ReSS-LIVE.jsp](https://professional.heart.org/professional/EducationMeetings/MeetingsLiveCME/ScientificSessions/UCM_488605_Sessions-ReSS-LIVE.jsp).

In connection with the presentation of such results, Amarin plans to issue a press release describing the trial results.

Presentation of the REDUCE-IT clinical trial results is scheduled immediately following presentation and discussion of results from a clinical trial known as VITAL. VITAL is an NIH-funded trial of vitamin D3 and 1 gram of an omega-3 mixture (prescription Lovaza) for the primary prevention of cancer and cardiovascular disease in a nationwide United States cohort of 25,874 adults not selected for elevated cardiovascular or cancer risk. Amarin does not know the results of the VITAL study. In the past, including results of the ASCEND study reported earlier this year, omega-3 mixtures have not demonstrated significant cardiovascular benefit on top of contemporary medical therapy. These results with omega-3 mixtures have not shown benefit and differ from the success reported with the unique single active ingredient in Vascepa in the REDUCE-IT study and a similar product in the JELIS study conducted in Japan.

#### Amarin Investor/Analyst Conference Call

Amarin today announced that it plans to hold a meeting Saturday at 7:15 p.m. CT / 8:15 p.m. ET with investors and analysts who are attending AHA to discuss the results of the trial presented earlier in the day. Amarin intends to broadcast this meeting live via webcast. The meeting will include comments from representatives of Amarin.

This call will commence at the time shown above. The webcast will be accessible through the investor relations section of the company's website at [www.amarincorp.com](http://www.amarincorp.com). The call can also be heard via telephone by dialing 877-407-8033. A replay of the call will be made available for a period of two weeks following the conference call. To hear a replay of the call, dial 877-481-4010 (inside the United States) or 919-882-2331 (outside the United States). A replay of the call will also be available through the company's website shortly after the call. For both dial-in numbers please use conference ID 39894.

Investors and analysts who are attending AHA and who wish to attend this meeting in person should inform Elisabeth Schwartz per the contact information below. Space at the meeting will be limited.

#### Continuing Medical Education Programs

Two live independently conducted continuing education programs for healthcare professionals are scheduled during AHA with discussion of REDUCE-IT results known to be part of their curriculum. Space in these CME programs is limited. Information regarding these CME programs is available via the websites of the organizers of the programs. Accessibility to such programs via webcast live or on an enduring basis is being evaluated by the organizers. The organizers are Medtelligence and Vindico, respectively. Information regarding the Sunday evening event is available at <http://events.medtelligence.net/ha18htg.html>. Information regarding the Monday morning event is available at <https://www.eventbrite.com/e/advancing-science-in-residual-cardiovascular-risk-will-new-cardiovascular-outcomes-trials-bring-a-registration-51595011067>. Amarin provided an unrestricted educational grant to support these programs, however, Amarin is not responsible for the organization or content of these presentations. Amarin does not control individual access to such programs. Description of these programs here is provided for informational purposes reflecting the interest level in REDUCE-IT results. No material new information is expected to be presented in these programs.

## 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 lipid science and the potential therapeutic benefits of polyunsaturated fatty acids. 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](http://www.amarincorp.com).

## About REDUCE-IT

The REDUCE-IT cardiovascular outcomes study commenced in 2011, enrolled and followed 8,179 randomized patients, and was conducted based on a special protocol assessment agreement with FDA.

REDUCE-IT is the first global cardiovascular outcomes study to prospectively evaluate the effect of Vascepa, or any therapy, 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 TGs between 150-499 mg/dL (median baseline 216 mg/dL) and either established cardiovascular disease (secondary prevention cohort) or diabetes mellitus and at least one other CV risk factor (primary prevention cohort). The design of the REDUCE-IT cardiovascular outcomes study was published in March 2017 in *Clinical Cardiology*<sup>1</sup> and can be found in the R&D section on the company's website at [www.amarincorp.com](http://www.amarincorp.com).

The REDUCE-IT hypothesis tested whether additional cardiovascular risk reduction beyond LDL-C controlled with statin therapy could be achieved in high risk patients with the putative cardioprotective effects of Vascepa 4 grams/day. Independent of REDUCE-IT, Amarin has worked to further support the REDUCE-IT hypothesis with published scientific findings based on various degrees of evidence that show EPA may interrupt the atherosclerotic process (e.g., plaque formation and instability) by beneficially affecting cellular functions thought to contribute to atherosclerosis and cardiovascular events and by beneficially affecting lipid, lipoprotein and inflammation biomarkers.<sup>2, 3, 4, 5, 6</sup>

## 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.<sup>7, 8</sup>

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.<sup>9, 10, 11, 12</sup>

## 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. 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 ( $\geq 500$  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](http://WWW.VASCEPA.COM).

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 ( $\geq 500$  mg/dL) hypertriglyceridemia. 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.

## Forward-Looking Statements

This press release contains forward-looking statements, including expectations regarding scientific presentation. 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, 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 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 (<http://www.amarincorp.com/>), the investor relations website (<http://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.

#### References

- <sup>1</sup> Bhatt DL, Steg PG, Brinton EA, Jacobson TA, Miller M, Tardif J-C, Ketchum SB, Doyle RT Jr, Murphy SA, Soni PN, Braeckman RA, Juliano RA, Ballantyne CM and 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.
- <sup>2</sup> Ganda OP, Bhatt DL, Mason RP, et al. Unmet need for adjunctive dyslipidemia therapy in hypertriglyceridemia management. *J Am Coll Cardiol.* 2018;72(3):330-343.
- <sup>3</sup> Borow KM, Nelson JR, Mason RP. Biologic plausibility, cellular effects, and molecular mechanisms of eicosapentaenoic acid (EPA) in atherosclerosis. *Atherosclerosis.* 2015;242(1):357-366.
- <sup>4</sup> Nelson JR, Wani O, May HT, et al. Potential benefits of eicosapentaenoic acid on atherosclerotic plaques. *Vascul Pharmacol.* 2017;91:1–9.
- <sup>5</sup> Mason RP, Dawoud H, Jacob RF, et al. Eicosapentaenoic acid improves endothelial function and nitric oxide bioavailability in a manner that is enhanced in combination with a statin. *Biomed Pharmacother.* 2018;103:1231-1237.
- <sup>6</sup> Takamura M, Kurokawa K, Ootsuji H, et al. Long-term administration of eicosapentaenoic acid improves post-myocardial infarction cardiac remodeling in mice by regulating macrophage polarization. *J Am Heart Assoc.* 2017;6(2). pii: e004560.
- <sup>7</sup> American Heart Association. 2018. Disease and Stroke Statistics-2018 Update.
- <sup>8</sup> American Heart Association. 2017. Cardiovascular disease: A costly burden for America projections through 2035.
- <sup>9</sup> Budoff M. Triglycerides and triglyceride-rich lipoproteins in the causal pathway of cardiovascular disease. *Am J Cardiol.* 2016;118:138-145.
- <sup>10</sup> Toth PP, Granowitz C, Hull M, et al. High triglycerides increase cardiovascular events, medical costs, and resource utilization in a real-world analysis of statin-treated patients with high cardiovascular risk and well-controlled low-density lipoprotein cholesterol [abstract]. *Circulation.* 2017;136(suppl 1):A15187.
- <sup>11</sup> Nordestgaard BG. Triglyceride-rich lipoproteins and atherosclerotic cardiovascular disease - New insights from epidemiology, genetics, and biology. *Circ Res.* 2016;118:547-563.
- <sup>12</sup> Nordestgaard BG, Varbo A. Triglycerides and cardiovascular disease. *Lancet.* 2014; 384: 626–635.

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