

# Amarin Corporation

## Important New Data on Vascepa® (Icosapent Ethyl) from the REDUCE-IT™ Trial to Be Presented Regarding Reduction in Total Ischemic Events

March 4, 2019

### Multiple Scientific Presentations Scheduled for American College of Cardiology's 68th Annual Scientific Session

#### Amarin to Webcast Discussion of Presented Data March 18, 4:00-5:00 pm Central Time

BEDMINSTER, N.J., and DUBLIN, Ireland, March 04, 2019 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), a pharmaceutical company focused on improving cardiovascular health, is supporting the presentation of six accepted scientific presentations at the American College of Cardiology's (ACC) 68th Annual Scientific Session from March 16-18, 2019 in New Orleans, LA.

An Amarin investor/analyst conference call to discuss the presented data, including data from the late-breaker presentation, will be held on Monday, March 18 at 4:00 p.m. Central Time (CT) / 5:00 p.m. Eastern Time (ET) with several prominent physicians.

"Amarin remains committed to generating important new information about the epidemiology and treatment of patients with residual cardiovascular risk beyond LDL-C management to advance the medical community's understanding of relevant factors to improve patient care," said Craig B. Granowitz, M.D., Ph.D., senior vice president and chief medical officer of Amarin. "The accepted ACC presentations sponsored by Amarin are a further demonstration of Amarin's leadership in this area."

#### Data to be presented includes:

##### Late-Breaking Clinical Trial

- *Reduction in Total Ischemic Events with Icosapent Ethyl in REDUCE-IT™* Deepak L. Bhatt, Philippe Steg, Michael Miller, Eliot Brinton, Terry Jacobson, Steven Ketchum, Ralph Doyle, Rebecca Juliano, Lixia Jiao, Craig Granowitz, Jean Claude Tardif, John Gregson, Stuart Pocock, and Christie Ballantyne, for the REDUCE-IT Investigators  
Original Presentation 409-16. March 18, 9:00 to 9:10 am Central Time (CT) in the Main Tent (Great Hall)

Follow-up, Deep Dive II Presentation 412-16. March 18, 1:30 to 1:35pm Central Time (CT) in Room La Nouvelle C

##### Poster Presentations

- *Eicosapentaenoic Acid Inhibits Membrane Lipid Oxidation in a Concentration-Dependent Manner at Pharmacologic Doses In Vitro.* R. Preston Mason, and Samuel C. R. Sherratt  
Presentation 1180-452 / 452. March 16, 3:45 PM - 4:30 PM CT in Poster Hall F
- *Burden of Atherosclerotic Cardiovascular Disease Risk in Persons with Elevated Triglyceride Levels According to Statin Use.* Nathan D. Wong, Wenjun Fan, Sephy Philip, Craig Granowitz, and Peter Toth  
Presentation 1178-417 / 417. March 16, 3:45 PM - 4:30 PM CT in Poster Hall F
- *Long-term Statin Persistence Is Poor Among High-Risk Patients with Baseline Peripheral Artery Disease: A Real-World Administrative Claims Analysis of the Optum Research Database.* Peter P. Toth, Craig Granowitz, Michael Hull, and Sephy Philip  
Presentation 1134-435 / 435. March 16, 10:00 AM - 10:45 AM CT in Poster Hall F
- *Triglycerides as a Risk Factor for Coronary Heart Disease: What Measure and What Cutoff?* Ann Marie Navar, Neha Pagidipati, Hillary Mulder, Tsion Abera, Sephy Philip, Craig Granowitz, and Eric Peterson  
Presentation 1331-414 / 414. March 18, 9:45 AM - 10:30 AM CT in Poster Hall F
- *Increased Residual Cardiovascular Risk in US Veterans and Moderately-Elevated Baseline Triglycerides and Well-Controlled LDL-C Levels on Statins.* Sarah Leatherman, Ryan Ferguson, Isabelle Weir, Cynthia Hau, Craig Granowitz, Kelly Harrington, Sephy Philip, Peter Toth, Deepak L. Bhatt, and William Boden  
Presentation 1060-09. March 18, 1:15 PM - 1:25 PM CT in Prevention Moderated Poster Theater Poster Hall F

#### Amarin Investor/Analyst Conference Call

Amarin plans to hold a call on Monday, March 18 at 4:00 p.m. Central Time CT / 5:00 p.m. ET for investors and analysts to discuss the results presented in the late-breaker session and some of the poster data presented earlier in the day. Amarin intends to broadcast this meeting live via webcast.

This call will commence at the time shown above and will be accessible via webcast 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 44518.

### **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](http://www.amarincorp.com).

### **About REDUCE-IT**

REDUCE-IT<sup>1</sup>, an 8,179-patient cardiovascular outcomes study, was completed in 2018. REDUCE-IT was a multinational cardiovascular outcomes study that 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](http://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.<sup>2, 3</sup>

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.<sup>4</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>5, 6, 7, 8</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 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 ( $\geq 500$  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 statements related to timing and announcements with respect to the subject clinical data. 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 research

and development; clinical trials and related regulatory approvals; 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. The American College of Cardiology reserves the right to change or rescind its invitation to present any and all clinical trial results. 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 (<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, Miller M, Brinton EA, Jacobson TA, Ketchum SB, Doyle RT, Juliano RA, Jiao L, Granowitz C, Tardif JC, Ballantyne CM. Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglyceridemia. *N Engl J Med* 2019;380:11-22.
- <sup>2</sup> American Heart Association. 2018. Disease and Stroke Statistics-2018 Update.
- <sup>3</sup> American Heart Association. 2017. Cardiovascular disease: A costly burden for America projections through 2035.
- <sup>4</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>5</sup> Budoff M. Triglycerides and triglyceride-rich lipoproteins in the causal pathway of cardiovascular disease. *Am J Cardiol*. 2016;118:138-145.
- <sup>6</sup> Toth PP, Granowitz C, Hull M, et al. High triglycerides are associated with increased cardiovascular events, medical costs, and resource use: A real-world administrative claims analysis of statin-treated patients with high residual cardiovascular risk. *J Am Heart Assoc*. 2018;7(15):e008740.
- <sup>7</sup> Nordestgaard BG. Triglyceride-rich lipoproteins and atherosclerotic cardiovascular disease - New insights from epidemiology, genetics, and biology. *Circ Res*. 2016;118:547-563.
- <sup>8</sup> Nordestgaard BG, Varbo A. Triglycerides and cardiovascular disease. *Lancet*. 2014;384:626-635.

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Source: Amarin Corporation plc