

# Amarin Corporation

## High Risk of Atherosclerotic Cardiovascular Events Projected in People with Elevated Triglycerides Without Established Atherosclerotic Cardiovascular Disease

March 16, 2019

BEDMINSTER, N.J. and DUBLIN, Ireland, March 16, 2019 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN), a pharmaceutical company focused on improving cardiovascular health, announced today the presentation of data and analysis which concluded that over nine million atherosclerotic cardiovascular disease (ASCVD) events are projected to occur in the United States within the next ten years in adults aged 40-79 for whom ASCVD is not established. Over three million of these events are projected to occur in persons with elevated triglyceride (TG) levels of  $\geq 150$  mg/dL, including approximately one million events in statin users. The research used a risk calculator to estimate 10-year risk and reported that increased cardiovascular (CV) risk was proportionally greater among persons with higher TG levels. This research highlights that millions of CV events will occur in people that haven't had a CV event and supports the need for expanded education about the use of TG levels as an identifier of cardiovascular risk. It also highlights that there is an urgent need to address this immense risk and examine the capacity of lifestyle modification and other therapies to attenuate ASCVD risk beyond cholesterol management in patients with elevated TG levels.

These data and analysis were presented in a poster entitled "*Burden of Atherosclerotic Cardiovascular Disease Risk in Persons with Elevated Triglyceride Levels According to Statin Use*" at the American College of Cardiology's (ACC) 68<sup>th</sup> Annual Scientific Session in New Orleans, LA. The research used the ACC/AHA risk calculator and NHANES data with corresponding projected population sizes to estimate a 10-year risk of cardiovascular death, nonfatal myocardial infarction (MI or heart attack), or fatal/nonfatal stroke in people without established atherosclerotic cardiovascular disease (ASCVD). The analysis did not include other major adverse cardiovascular events such as by-pass surgery, stents or hospitalization for angina.

"This presentation underscores that people with elevated triglycerides without established cardiovascular disease are at a high risk for cardiovascular events," stated John F. Thero, president and CEO of Amarin. "While lowering triglyceride levels alone without reducing other cardiovascular risks may be insufficient to significantly lower cardiovascular risk, elevated triglyceride levels provide a means of identifying patients with increased cardiovascular risk beyond cholesterol levels. We encourage people to recognize this risk and to discuss elevated triglyceride levels with their medical professionals."

This poster was authored by Nathan D. Wong, Wenjun Fan, Sephy Philip, Craig Granowitz, and Peter Toth.

### Amarin Investor/Analyst Conference Call

Amarin plans to webcast live a physician panel discussion for investors and analysts on Monday, March 18 at 4:00 p.m. CT / 5:00 p.m. ET. During the panel discussion leading physicians are anticipated to review data pertaining to Vascepa presented at ACC's 68<sup>th</sup> Annual Scientific Session, including the scheduled presentation on Monday, March 18 at 9 a.m. CT / 10 a.m. ET in the late-breaker session regarding additional data from the REDUCE-IT cardiovascular outcomes study. The panel discussion may also cover data from the above described poster and from other posters presented at ACC.

This physician panel discussion 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 panel discussion can also be heard via telephone by dialing 877-407-8033. A replay of the panel discussion will be made available for a period of two weeks following the webcast. 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 panel discussion will also be available through the company's website shortly after the webcast. 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<sup>®</sup> (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 cardiovascular risk in patient groups based on data presented. 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 data of this type, research and development, clinical trials and related regulatory approvals. A list and description of uncertainties and 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, Julianio 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