

## **Amarin® Company History**

### **About Amarin®**

Amarin Corporation plc (Nasdaq: AMRN) was founded in 1993. In 2009, at the start of its Phase 3 clinical program for the prescription drug VASCEPA® (icosapent ethyl), the company became predominantly focused on solutions for preventative cardiovascular care. Today Amarin is a rapidly growing, innovative pharmaceutical company leading a new paradigm in cardiovascular health management and seeking to create a new standard of care for cost-effective cardiovascular risk reduction in high-risk patients.

Amarin is headquartered in Dublin, Ireland. In the United States, the company's primary office is in Bridgewater, N.J. Amarin employs more than 1,000 people.

### **Guided by Science, Driven to Improve Patient Care**

Amarin's product development program leverages its extensive experience and knowledge in polyunsaturated fatty acids, lipid science and in multiple factors contributing to cardiovascular disease. During the primary development phase of VASCEPA, which led to successful cardiovascular outcomes study results in 2018 that formed the basis of an FDA approval in 2019 for a cardiovascular risk reduction indication (described below), a disproportionately large portion of Amarin's resources were dedicated to research and development. The development of VASCEPA involved multiple clinical studies conducted over more than a decade at a cost of over \$700 million and involving more than 37,000 patient years of study.

Throughout this development period, Amarin recognized that cardiovascular disease is an enormous and growing healthcare issue; that there is a large unmet medical need to help more patients reduce the risk and potential resulting pain and cost of major adverse cardiovascular events (e.g. strokes and heart attacks); and that solutions are not easy, as other companies have failed trying. With this large unmet medical need as a motivator and by following scientific data, Amarin developed VASCEPA, which led to the first-ever FDA approval for any drug for cardiovascular risk reduction for the at-risk patient population indicated in the prescribing information for VASCEPA.

Amarin's accomplishments have only been possible through the dedication and passion of its employees and collaborators as well as through the financial support of its investors.

### **Commercialization**

Amarin's lead product, VASCEPA (icosapent ethyl), is approved by the United States Food and Drug Administration (FDA) and available by prescription in the United States, where it is marketed solely by the company. Outside the United States, VASCEPA is approved and promoted via a commercial partner in Lebanon and the United Arab Emirates. Amarin, together with its commercial partners in select geographies, is pursuing additional regulatory approvals for VASCEPA in Canada, China, the European Union and the Middle East.

In 2013, Amarin launched VASCEPA in the United States for an important niche indication of lowering triglyceride levels in patients with very high triglycerides ( $\geq 500$  mg/dL), a medical condition associated with the risk of pancreatitis. Since becoming available in 2013, VASCEPA

has been prescribed more than 8 million times and is covered by most major medical insurance plans.

In 2019, following the successful completion of a large multinational cardiovascular outcomes study for VASCEPA, Amarin began to expand its commercialization efforts in the United States, including doubling the size of the company's sales team to 400 sales representatives. In December 2019, the FDA approved VASCEPA for an expanded indication of cardiovascular risk reduction. As a result, Amarin's U.S. sales force is increasing to approximately 800 sales representatives in early 2020 to launch the new expanded label for VASCEPA, with the aim of helping millions of high-risk patients reduce their risk of incurring a major adverse cardiovascular event, such as a stroke or heart attack.

### **How is Amarin Different?**

Amarin is a small company achieving great things through focus, science and passion.

The significant cardiovascular risk reduction demonstrated with VASCEPA through extensive clinical study has been heralded as one of the most significant breakthroughs in preventative cardiovascular care since statin therapy was introduced nearly three decades ago. Prior to these clinical results, it was generally believed outside of Amarin that such a breakthrough was not possible. Such views were supported by failed studies of other drugs from various companies who also sought to reduce the persistent cardiovascular risk which remains even after a patient is treated with current standard-of-care therapies, such as cholesterol management with statin medication. Now, Amarin is working to make VASCEPA available to help millions of people based on its new FDA-approved indication.

Despite being the only FDA-approved drug for its indication, Amarin has elected to price VASCEPA at a level which is considerably lower than various other new cardiovascular drugs and has been working with insurers to help provide access to all patients in need. Amarin is proud that third-party analyses have concluded that VASCEPA is cost effective, a result rarely achieved in such analyses.<sup>1,2</sup>

### **About VASCEPA®**

The active ingredient in VASCEPA is icosapent ethyl. This unique ingredient is believed to have multiple clinical effects, the results of which have demonstrated cardiovascular risk reduction in high-risk patients.

In the United States, VASCEPA is FDA-approved 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 ( $\geq 150$  mg/dL) and established cardiovascular disease or diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.
- An adjunct to diet to reduce TG levels in adult patients with severe ( $\geq 500$  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 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 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  $\geq 3\%$  and  $\geq 1\%$  more frequent than placebo): musculoskeletal pain, peripheral edema, constipation, gout and atrial fibrillation.
- Common adverse reactions in the hypertriglyceridemia trials (incidence  $\geq 1\%$  more frequent than placebo): arthralgia and oropharyngeal pain.
- 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 for bleeding should be monitored.

**FULL VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT  
[WWW.VASCEPA.COM](http://WWW.VASCEPA.COM).**

**For more information about Amarin, visit [www.amarincorp.com](http://www.amarincorp.com).  
For more information about VASCEPA, visit [www.vascepa.com](http://www.vascepa.com).**

This document is intended for use in media briefings only. This document is not intended for detailing or distribution to non-consultant HCPs, sales professionals or patients.

© 2019 Amarin Pharma, Inc.

---

1 Cost-Effectiveness of Icosapent Ethyl in REDUCE-IT. <https://www.abstractsonline.com/pp8/#!/7891/presentation/35097>.

2 [https://icer-review.org/wp-content/uploads/2019/02/ICER\\_CVD\\_Final\\_Evidence\\_Report\\_10.17.19.pdf](https://icer-review.org/wp-content/uploads/2019/02/ICER_CVD_Final_Evidence_Report_10.17.19.pdf).