What are Amarin's plans and timing for Vascepa® in Europe?

Amarin believes that the need for preventive cardiovascular care beyond currently available therapy is large in Europe, as it is throughout the world. In Europe, there are more than 80 million people living with cardiovascular disease. This number is growing with approximately 11 million new cases of cardiovascular disease added each year in EU countries. Cardiovascular disease results in approximately 1.8 million deaths each year in Europe on top of large numbers of debilitating events such as strokes and heart attacks resulting from cardiovascular disease.[1]

Caring for cardiovascular disease in Europe is expensive with annual spending estimated to currently exceed 200 billion Euro annually.[1] This significant public health burden, combined with the availability of cardiovascular outcomes study results with VASCEPA®, likely contributed to the clinical practice guidelines updated in 2019 by the European Society of Cardiology (ESC) and the European Atherosclerosis Society (EAS) recommending use of icosapent ethyl.[2,3] Numerous key opinion leaders in Europe are urging for the approval of VASCEPA in Europe to help them improve care for their patients.

Amarin intentionally did not seek approval for VASCEPA in Europe based on the triglyceride-lowering indication sought and obtained in the United States. By foregoing that niche market opportunity, assuming that VASCEPA is approved for the broader cardiovascular risk indication being pursued in Europe, VASCEPA is positioned to qualify for 10 to 11 years of regulatory exclusivity in Europe. In addition, patents for VASCEPA in Europe are anticipated to extend until mid-2033.

On December 2, 2019 Amarin announced that the European Medicines Agency (EMA) validated the marketing authorization application (MAA) seeking approval for icosapent ethyl (brand name VASCEPA in the United States) as a treatment to reduce the risk of cardiovascular events in high-risk patients who have their cholesterol levels controlled with statin treatment, but have elevated triglycerides, 135 mg/dL or above, and other cardiovascular risk factors. Validation confirmed the submission for VASCEPA is adequate for the EMA to begin its review procedure.

Amarin is planning for the EMA review process to be completed near the end of 2020 and result in approval of VASCEPA as the first and only drug for the preventative cardiovascular care indication being sought by Amarin.

In Amarin's landmark REDUCE-IT® cardiovascular outcomes global study, patient enrollment from Europe was second in aggregate number only to the patient enrollment in the United States. Amarin's MAA was made as a centralized procedure filing for Europe, and the co-rapporteurs assigned by the EMA for review of this submission are Germany and Estonia. Unlike in the U.S., where there is an established target date for completion of the regulatory review process, the regulatory review process in Europe is adjusted along the process based on the scope of questions asked by reviewers and the time required for the sponsor to adequately respond to such questions. After anticipated regulatory approval of VASCEPA via the centralized procedure in Europe, it will be necessary, as is typical, to pursue payor coverage (mostly governmental) on a country-by-country basis.

Although VASCEPA is not yet approved for sales in the European Union, in August 2019 the ESC and the EAS jointly updated clinical practice guidelines to include icosapent ethyl (VASCEPA) to address high-risk cardiovascular patients with elevated triglycerides (135-499 mg/dL).[2,3] The classification is a Level B recommendation which reflects a relatively high weight of scientific evidence under ESC and EAS standards.

In March 2020, after initial feedback from the EMA's review of Amarin's MAA, Amarin commenced a process for evaluating potential commercial partners for VASCEPA in Europe. In parallel, Amarin has been evaluating its prospects for launching VASCEPA directly in some or all countries in Europe. Whether to partner VASCEPA for commercialization in Europe, launch directly, or proceed with a hybrid of the two approaches is not yet decided. Amarin intends to review potential proposals from prospective partners before making this decision. Amarin is currently targeting making this decision regarding the best commercialization pathway for VASCEPA in Europe in the third calendar quarter of 2020. When this decision is made, Amarin intends to announce it.

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[1] http://www.ehnheart.org/cvd-statistics.html
[2] European Society of Cardiology https://www.escardio.org/The-ESC/Who-we-are
[3] European Atherosclerosis Society https://www.eas-society.org/page/about_eas