

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

Amarin believes that there is a large potential opportunity for *Vascepa* in Europe as heart disease is a large and growing health care burden throughout the world. 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. The validation confirmed the submission for *Vascepa* is adequate for the EMA to begin its review procedure, which is currently expected to be completed before the end of 2020.

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 European Society of Cardiology (ESC) and the European Atherosclerosis Society (EAS) jointly updated patient treatment guidelines to include icosapent ethyl (*Vascepa*) to address high-risk cardiovascular patients with elevated triglycerides (135-499 mg/dL). The classification is a Level B recommendation which reflects a relatively high weight of scientific evidence under ESC and EAS standards.

Amarin intends to evaluate potential commercial partners for *Vascepa* in Europe after progressing the MAA through initial review by the EMA and after launch of *Vascepa* in the United States for a cardiovascular risk reduction indication, subject to approval by the U.S. Food and Drug Administration which approval in the United States is anticipated on or before December 28, 2019 with launch in the United States for this new indication commencing in early 2020.

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