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. Amarin is planning to submit to the European Medicines Agency (EMA) by the end of 2019 an application seeking authorization to market *Vascepa* for cardiovascular risk reduction based on the results of the landmark REDUCE-IT® cardiovascular outcomes study. In that global study, patient enrollment from Europe was second in aggregate number only to the patient enrollment in the United States. Amarin is planning a centralized procedure filing for Europe, and the co-rapporteurs assigned by the EMA for review of this submission are Germany and Estonia. The anticipated regulatory approval timeline for Europe can be better assessed after the submission is made to and accepted by the EMA. In general, a one-year review for this EU regulatory submission is anticipated. 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. The pathway for "accelerated assessment" in Europe is not available for *Vascepa*, as that limited pathway is typically reserved for therapies addressing acute life-threatening conditions rather than chronic medical conditions. After assumed 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. Amarin top priorities for *Vascepa* are securing regulatory approval for a cardiovascular risk reduction indication in the U.S. and ensuring a successful launch of *Vascepa* for that expanded indication in the U.S. After this process has progressed further in the U.S. and after the regulatory submission is submitted in Europe and review of such submission is confirmed to be advancing as anticipated, Amarin will give greater priority to commercialization plans in Europe, including consideration of various commercial partner opportunities.

Dated: October 21, 2019