What is Amarin's position on The Institute for Clinical and Economic Review (ICER) final report on the cost effectiveness and value of Vascepa®?

On October 17, 2019, ICER, an independent non-profit organization, released its final report on the clinical effectiveness and economic impacts of Vascepa® (icosapent ethyl). ICER's report confirms the cost effectiveness of Vascepa across all of the non-profit organization's analyses, based on its Quality-adjusted life year (QALY) metrics of <\$50,000.

The review was derived from results of the landmark phase 3 clinical trial REDUCE-IT^{*1}, focusing on the clinical benefit-risk profile of Vascepa and its value as an additive therapy for cardiovascular disease. The conclusion from the report is that Vascepa easily meets "commonly cited thresholds for cost-effectiveness and therefore represent a high long-term value for money," based on the organization's value assessment framework.

Despite the report's positive conclusion regarding cost effectiveness, we believe that ICER understates the value of Vascepa. For example, the ICER base-case analyses reflect only the costs of heart attack, stroke and cardiovascular death and appear to exclude high costs associated with other cardiovascular events that were demonstrated to be lowered by Vascepa in the REDUCE-IT cardiovascular outcomes study (e.g., revascularization procedures and hospitalization for unstable angina), and did not take into account lower rates of recurring cardiovascular events in patients treated with Vascepa during the study.

Cardiovascular disease is the No. 1 cause of death in the United States. We believe that millions of at-risk statin-treated patients with elevated triglycerides can benefit from the preventive-care solution demonstrated by Vascepa in REDUCE-IT.

Dated October 17, 2019

¹ Bhatt DL, Steg PG, Miller M, et al. Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglyceridemia. N Engl J Med 2019;380:11-22.

² American Heart Association. 2017. Cardiovascular Disease: A Costly Burden for America Projections Through 2035.