What is Amarin's perspective on the potential for competitors to use changes in biomarkers demonstrated in clinical trials of Vascepa®, such as triglyceride (TG) level reduction, as a means of establishing the clinical effect of their drugs by making comparisons to such biomarker effects as an attempt to associate their products with Vascepa's demonstrated results in the REDUCE-IT® cardiovascular outcomes study?

As supported by third-party medical guidelines and publications of REDUCE-IT results, the results of Vascepa clinical studies cannot be generalized to any other product within or outside the omega-3 class. Moreover, other products that lower TG levels have failed in cardiovascular outcomes studies to demonstrate reductions in cardiovascular events. The clinical effects of Vascepa are unique and multifactorial going well beyond TG lowering. Additionally, results in the REDUCE-IT study were observed to be independent of baseline TG levels for enrolled patients in the study that were above or below 150 mg/dL.

Because of these factors, comparisons of Vascepa with other therapies based on relative impact on TG levels, for example, cannot be relied upon to assess the effect of such products on cardiovascular risk reduction. The REDUCE-IT study demonstrated the clinical effects of Vascepa in high risk, statin treated patients with persistent elevated TG levels. REDUCE-IT did not validate the hypothesis that drug-induced TG lowering effects, generally, lower cardiovascular risk. It is likely that sponsors of other products seeking to demonstrate that they too lower cardiovascular risk will need to demonstrate that their products are safe and effective through a long-term cardiovascular outcomes study. Historically other therapies have failed to demonstrate such a benefit. Achieving favorable results from a cardiovascular outcomes study requires multiple years and significant financial resources. Given the above factors, attempts to suggest comparative effects in cardiovascular risk reduction based on comparative effects in biomarkers such as triglyceride reduction should be viewed with significant caution.

(updated July 1, 2019)