

Question: What is Amarin's perspective regarding the complete response letter that Novartis received regarding its drug canakinumab as a potential treatment for cardiovascular risk reduction?

The complete response letter (CRL) is not public. It is a communication between the FDA and Novartis. Accordingly, we do not know if the CRL pertains to efficacy, safety, manufacturing or other concerns. It is public information that in the CANTOS study, canakinumab met all of the prespecified multiplicity-adjusted thresholds for statistical significance at only the 150 mg dose. And, in public presentations, results of the study have been presented based on exploratory endpoints related to on-treatment hsCRP changes. We do not know if these factors contributed to the CRL.

In contrast, the REDUCE-IT study was designed under a special protocol assessment agreement with the FDA. And, as separately disclosed, topline results for the REDUCE-IT study show that the study achieved its primary endpoint with statistical significance. Amarin does not believe that the CRL received by Novartis for canakinumab will impact the FDA's review of a supplemental NDA for Vascepa. The drugs are different, the clinical trials were different and the clinical trial results are different.