If a posting is made that an upcoming medical congress (e.g., meeting of a medical society for scientific review) will include a presentation regarding an ongoing clinical study or other data which has not yet been publicly presented, does this mean that the medical society and Amarin have seen the data in advance of the scheduled presentation and, if yes, why doesn't Amarin present such data earlier?

Presentation of clinical and other scientific research results, whether or not they are supported or sponsored by Amarin, is often done at medical congresses. Doing so ensures that such data receives attention and peer-review from the medical community, both of which are important to the long-term success of a drug, assuming that the data is reliable and may have clinical utility. For scheduling purposes, securing presentation opportunities at medical congresses is typically done well in advance. Such scheduling also may be done in advance of knowing the actual clinical trial results that will be presented.

Generally, medical congresses are interested in hosting first presentations of new or novel data. The organizers do not always see the clinical data when scheduling occurs. Rather, they rely on a description of the trial design, methods, and prespecified endpoints to determine the relevance and acceptability of data for future presentation. When the organizers of a medical congress accept and schedule a scientific presentation as a feature of their upcoming event, such as a late-breaker presentation, they insist that the data to be presented is not made public prior to its presentation at the congress and they make it clear that the presentation will be cancelled if these rules are violated.

The pharmaceutical industry, including Amarin, has considerable experience in ensuring that data, once known, is confidentially maintained until the data is publicly released. Such data controls are often audited by the U.S. Securities and Exchange Commission to ensure that no investor is trading on material non-public information regarding clinical trials.

With regard to investigator-initiated clinical studies, which are clinical studies conducted by third-parties with the support of companies like Amarin, the clinical results often are not made available to the company during the conduct of the study. For example, Amarin has supported multiple investigator-initiated trials (IITs) pertaining to the potential use of VASCEPA® to help prevent COVID-19 infections and/or help mitigate the severity of such infections. These COVID-19 pilot studies have been separately described by Amarin [click here for FAQ]. Such IITs are conducted by leading healthcare professionals and research organizations using product (VASCEPA) supplied by Amarin. In these IITs, where Amarin is not the sponsor, the data collection, analysis and overall conduct of the studies are done independently of Amarin, and Amarin is blinded to the ongoing study results.

While Amarin is often made aware of efforts to schedule presentations of IIT-related information at medical congresses, Amarin is not party to such scheduling and it cannot predict in advance of such presentations the data that will be presented. Further, Amarin does not believe that it would be in the best interest of its shareholders for Amarin to undermine such a scientific presentation by speculating about or, if available, pre-releasing data prior to a scheduled presentation at a medical congress. Doing so would deprive the data from receiving the attention and scrutiny it deserves from the medical community and would likely creating unnecessary conflict with both the investigators conducting the clinical trial and the organizers of the medical congress.