

**What additional information is available to aid in understanding of the significance of clinical results from the VASCEPA COVID-19 CardioLink-9 Randomized Trial, which was presented as a Late Breaker Presentation at National Lipid Association (NLA) Scientific Sessions 2020 on December 12, 2020? A press release regarding such results can be found [here](#).**

Below is additional information to put the VASCEPA COVID-19 CardioLink-9 Randomized Trial results into appropriate context:

- *What is the purpose of FLU-PRO score in the VASCEPA COVID-19 CardioLink-9 Randomized Trial?*

The FLU-PRO score is a validated tool assessed through a questionnaire completed by patients that was originally developed by the NIH to standardize and comprehensively assess symptoms associated with various viruses across multiple body symptoms. While the FLU-PRO score tool was developed prior to COVID-19, it is believed to be relevant to assessing severity of COVID-19 infection symptoms. It was developed using qualitative and quantitative methods consistent with scientific measurement standards and United States Food and Drug Administration (FDA) and European Medicines Agency (EMA) guidelines for clinical outcome assessments.

While the FLU-PRO score has been the basis of clinical studies of various therapies, it is subject to the limitations associated with any patient questionnaire. Biomarker assessment and analysis conducted in parallel with the FLU-PRO score can help in assessing the reliability of the FLU-PRO score results.

- *What are inflammatory biomarkers and which ones are relevant to COVID-19?*

Inflammation is a common symptom in COVID-19 infected patients.

Inflammatory markers are biological indicators in a blood or other tests that detect levels of inflammation in the body.

Inflammatory markers can help with diagnosis or classification of patient risk to facilitate treatment decisions. Examples of inflammatory and other biomarkers understood to be often implicated in COVID-19 infected patients include the following: High-sensitivity C-reactive protein (hsCRP), D-dimer, troponin, creatine kinase and platelets.

- *What is D-dimer and what relevance does it have to COVID-19?*

D-dimer is one of the protein fragments produced when plasmin cleaves fibrin during the process of a blood clot being dissolved in the body. Reasons for D-dimer elevations in COVID-19 infected patients are not fully understood, but are thought to signify a hyperfibrinolysis state and increased inflammatory burden induced in SARS-COV-2 infection.

D-dimer tests are often used to help identify blood clotting disorders. In COVID-19 infected patients, it is believed, but not proven, that lowering of D-dimer is associated with improved health.

- *What is hsCRP, or high-sensitivity C- reactive protein, and what relevance does it have on COVID-19?*

C-reactive protein (CRP) is a marker of systemic inflammation, and a high-sensitivity CRP (hsCRP) test may be used to help evaluate an individual at risk for diseases affected by high inflammatory states, such as cardiovascular disease (CVD). High-sensitivity CRP is often elevated in COVID-19 infected patients. In COVID-19 infected patients, it is believed, but not proven, that lowering hsCRP is associated with improved health.

- *What is the difference between a vaccine and a therapeutic?*

Vaccines are used as preventative measures to prepare the body's immune system to fight off infection. An example of a COVID-19 vaccine is the mRNA vaccine by Pfizer, which was recently granted emergency use authorization by the FDA to help prevent COVID-19 infections.

Therapeutics are designed to treat illness, to improve and manage a patient's symptoms, or to reduce a patient's risk for or severity of an illness. Therapeutics exist for a broad range of ailments ranging from the common cold (e.g. Theraflu) to COVID-19 (e.g., remdesivir and dexamethasone).

Some therapeutics are available only by prescription and others are available as over-the-counter options. Some are for in-hospital use only and others are for at-home use. In all cases, therapeutics require regulatory review and approval before they can be promoted and sold for that purpose.

- *Is Amarin conducting additional studies of VASCEPA in the context of COVID-19?*

Yes, additional information about other studies examining the use of VASCEPA in the context of COVID-19 is available here: <https://amarincorp.gcs-web.com/static-files/db64bd4e-1417-438f-be20-381de9358c40>

- *Is Amarin seeking patents that would cover the use of VASCEPA in the treatment of viral infections such as COVID-19?*

Yes, Amarin has been prosecuting patents targeted at protecting the use of VASCEPA in the treatment of a variety of disease conditions, including but not limited to COVID-19. Any such patents are expected to be distinct from Amarin patents covering uses demonstrated in separate clinical trials such as the MARINE, ANCHOR and REDUCE-IT clinical trials. The goal of any such patents would be to protect against infringing promotion and use of the active pharmaceutical ingredient of VASCEPA in such disease states. It typically takes many months before patent prosecution efforts are made public by the USPTO and other patent offices outside the United States. Once public, prosecution activity can be monitored through websites such as that administered by the USPTO. Patent prosecution is a time-consuming and technical process with often unpredictable results.