Why has an outcomes study not been conducted for patients with TG levels ≥500 mg/dL?

Multiple drugs are FDA approved for lowering TG levels ≥500 mg/dL, including Amarin's drug Vascepa® (icosapent ethyl). No outcomes study has been conducted in this population for any drug to demonstrate that lowering TG levels in this population lowers the risk of pancreatitis.

Amarin is committed to improved patient care. For example, Amarin completed the precedent-setting REDUCE-IT cardiovascular outcomes study demonstrating that Vascepa significantly lowers the risk of major adverse cardiovascular events, including death. However, conducting an outcomes study in patients with TG levels ≥500 mg/dL is difficult for reasons of ethics described below.

TG levels ≥500 mg/dL are considered very high TG levels. Guidelines for the management of very high TG levels suggest that reducing triglyceride levels is the primary goal in patients to reduce the risk of acute pancreatitis. The effect of Vascepa and other drugs on the risk for pancreatitis in patients with very high TG has not been determined.

Acute pancreatitis can lead to extreme levels of pain requiring emergency medical care and other medical complications, including death. It is considered impractical and unethical to conduct a clinical trial as part of which a group of patients is exposed to a risk when that risk has a generally accepted standard of care treatment that could prevent it. Suggestive but inconclusive data suggests that lowering very high TGs (at least 500 mg/dL) would prevent the risk developing acute pancreatitis. Accordingly, lowering TG levels in this patient population is a recognized basis for FDA approval. Lowering TG levels in this patient population with use of Vascepa is the basis for the current FDA-approved labeling for Vascepa.