approach
OPEN LABEL STUDY

About Familial Chylomicronemia Syndrome (FCS) and volanesorsen

Familial Chylomicronemia Syndrome (FCS) is a rare genetic disorder characterized by extremely high levels of triglycerides and the risk of recurrent, potentially fatal pancreatitis. People with FCS are unable to effectively clear large, triglyceride-rich lipid particles called chylomicrons due to a deficiency of lipoprotein lipase, an enzyme that helps break down triglycerides. Volanesorsen is an investigational new drug designed to prevent the formation of the protein apoC-III, a key regulator of triglycerides. Following completion of the APPROACH Clinical Trial, the pivotal phase 3 study of volanesorsen in FCS, researchers are now conducting the APPROACH Open Label Study to further assess the potential benefits of treatment with volanesorsen in patients.

About the APPROACH Open Label Study

- The APPROACH Open Label Study is a multi-center study to further evaluate the efficacy of volanesorsen measured by percent change in fasting triglyceride levels from baseline and to assess the durability of the efficacy with extended administration of volanesorsen.
- The study is enrolling participants with FCS who participated in previous volanesorsen clinical studies as well as patients with FCS who have not previously been enrolled in a trial.
- The APPROACH Open Label Study is open to adults (≥18) who have a confirmed diagnosis of FCS, a history of chylomicronemia, and fasting triglycerides ≥ 750 mg/dL (8.4 mmol/L) at screening. Other inclusion and exclusion criteria apply. For more information about eligibility, please visit https://clinicaltrials.gov/ct2/show/NCT02658175.
- Participation in the APPROACH Open Label Study will last approximately 65 weeks. Following an initial screening and assessment period, participants will receive volanesorsen via self-administered, subcutaneous injection once weekly for 52 weeks.
- Following the dosing period, patients will participate in a period of follow up involving blood tests and other measurements to assess the effects of treatment.

For information about APPROACH Open Label Study sites, please e-mail research@akceatx.com.

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