

Long-Term Safety and Efficacy of Plozasiran in Adults With Hypertriglyceridemia

NCT06822790

Status	RECRUITING
Phase	Phase 3
Sponsor	Arrowhead Pharmaceuticals
Enrollment	869 participants

Key Eligibility Criteria

Inclusion (12)

- Adult males, or nonpregnant (who do not plan to become pregnant), nonlactating adult females, who are able and willing to provide written informed consent prior to the performance of any study-specific procedures
- Completed all required study visits per protocol in the parent study
- Female subjects of childbearing potential must agree to use a highly effective method of contraception during the study and for at least 90 days after the End of Study (EOS) or the last dose of plozasiran, whichever is later. Male subjects must agree to use a condom during the study and for at least 90 days after the EOS or last dose of plozasiran whichever is later. Subjects must not donate sperm or eggs during the study and for at least 90 days after the EOS or last dose of plozasiran, whichever is later. Female subjects of childbearing potential on hormonal contraceptives must be stable on medication for >1 menstrual cycle prior to Day 1.
- Subjects must be on standard of care lipid and TG-lowering medications per local guidelines (unless documented as intolerant as determined by the Investigator, including an inability to safely administer or re-administer a specific drug because of fear, preference, genetic, clinical, or metabolic considerations, or due to a previous adverse reaction associated with, attributed to, or caused by specific drug)
- If the subject has a medical history of clinical atherosclerotic cardiovascular disease (ASCVD) or elevated 10-year ASCVD risk (eg, e7.5% per American Heart Association/American College of Cardiology [AHA/ACC] risk calculator for subjects e40 years of age or Framingham risk score calculator for subjects under the age of 40), the subject must be on appropriate lipid-lowering therapy as per local standard of care (ie, including moderate-to-high intensity statin, as indicated).

... and 7 more (see full listing online)

Exclusion (13)

- Subject was permanently discontinued from receiving plozasiran in the parent study due to elevated aspartate aminotransferase (AST) or alanine aminotransferase (ALT) or due to HbA1c elevation that did not respond to antidiabetic regimen
- Subject withdrew consent for continued study treatment in the parent study
- Known hypersensitivity to the active substance or to any of the excipients of plozasiran
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- Any new condition or worsening of existing condition or any other situation that in the Investigator's judgment, would make the subject unsuitable for enrollment, could interfere with the subject participating in or completing the study, would make it difficult to comply with protocol requirements, or put the subject at an additional safety risk

... and 8 more (see full listing online)

Locations (170 total)

Research Site 21, Bakersfield, California, United States
Research Site 9, Beverly Hills, California, United States
Research Site 11, Canoga Park, California, United States
... and 167 more locations

<https://clinicaltrials.gov/study/NCT06822790>

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