

Lp(a) Lowering Study of Pelacarsen (TQJ230) With Background Inclisiran in Participants With Elevated Lp(a) and Established ASCVD

NCT06813911

Status	RECRUITING
Phase	Phase 3
Sponsor	Novartis Pharmaceuticals
Enrollment	340 participants

Key Eligibility Criteria

Inclusion (7)

- Male and female participants 18 to $d80$ years of age at Screening visit
- Established ASCVD, defined as documented coronary heart disease (CHD), cerebrovascular disease (CVD), or peripheral arterial disease (PAD) at Screening visit
- On stable dose of local guideline recommended lipid lowering therapy for at least 30 days prior to Screening visit
- Participants must successfully complete the run-in period of background inclisiran treatment in order to be randomized
- On standard of care (SoC) treatment for other CVD risk factors including hypertension and diabetes for at least 30 days prior to Randomization/Baseline visit
- ... and 2 more (see full listing online)

Exclusion (12)

- Prior treatment with inclisiran
- Any other PCSK9 inhibitor (e.g., evolocumab, alirocumab) use within 4 months prior to Screening visit
- Uncontrolled hypertension at Randomization/Baseline visit
- Heart failure New York Heart Association (NYHA) class IV at Screening visit or at Randomization/Baseline visit (Day 1)
- Triglycerides ≥ 400 mg/dL at Screening visit
- ... and 7 more (see full listing online)

Locations (80 total)

Parkway Medical Center, Birmingham, Alabama, United States
Clinical Research Inst of Arizona, Sun City West, Arizona, United States
National Heart Institute, Beverly Hills, California, United States
... and 77 more locations