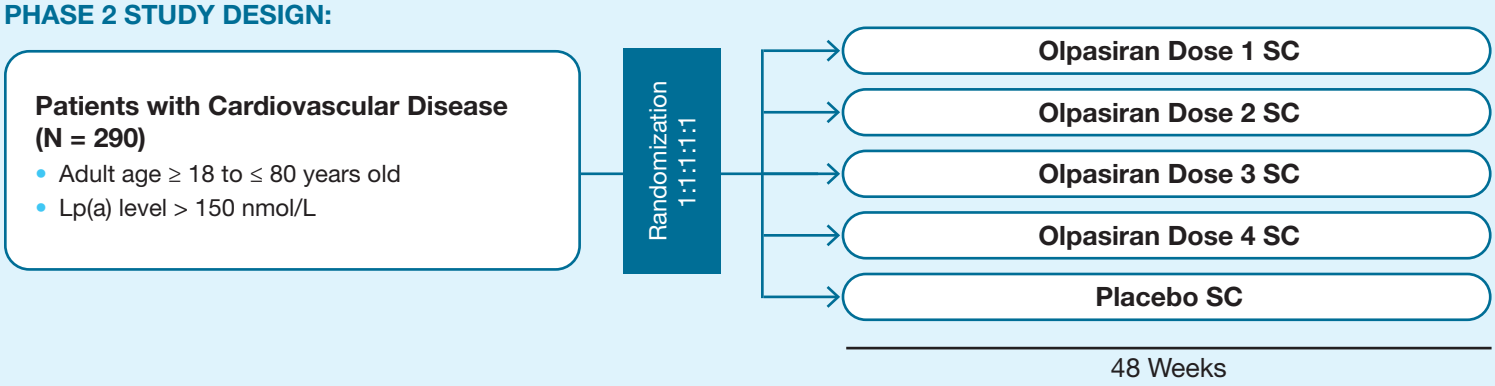
Olpasiran (AMG 890)

OCEAN(a)-DOSE
Olpasiran Trials of Cardiovascular Events And LipoproteiN(a) Reduction – DOSE Finding Study

Amgen Clinical Study: 20180109 NCT Clinical Study: NCT04270760

A Phase 2, Double-blind, Randomized, Placebo-controlled Study to Evaluate Efficacy, Safety, and Tolerability of Olpasiran (AMG 890) in Subjects With Elevated Lipoprotein(a)

PHASE 2 STUDY DESIGN:



STUDY PURPOSE:

Evaluate the effect of olpasiran administered subcutaneously (SC) compared with placebo, on percent change from baseline in Lp(a)

PRIMARY OUTCOME MEASURES:

- Percent change in Lp(a) from baseline to week 36

SECONDARY OUTCOME MEASURES:

- Percentage change in Lp(a) from baseline to week 48
- Percentage change in LDL-C from baseline to week 36 and week 48
- Percentage change in ApoB from baseline to week 36 and week 48
- Olpasiran pharmacokinetics (C_{max}, AUC)

KEY INCLUSION CRITERIA*:

- Adult age ≥ 18 to ≤ 80 years old
- Lp(a) level > 150 nmol/L
- Evidence of atherosclerotic cardiovascular disease

KEY EXCLUSION CRITERIA*:

- Estimated glomerular filtration rate (eGFR) < 30 mL/min/1.73 m^2
- History or clinical evidence of hepatic dysfunction
- Malignancy within the last 5 years
- Currently receiving, or less than 3 months at Day 1 since receiving > 200 mg/day Niacin

ADDITIONAL INFORMATION:

www.amgentrials.com (Protocol Number: 20180109) www.clinicaltrials.gov (Identifier: 04270760)

*Note: Not inclusive of all criteria.

ApoB = Apolipoprotein (B); AUC = area under the curve; C_{max} = maximum observed concentration; LDL-C = low-density lipoprotein cholesterol; Lp(a) = lipoprotein(a); SC = subcutaneous.

Olpasiran is an investigational drug. Efficacy and safety have not been established.

 USA-CCF-80134

AMGEN® Cardiovascular