

# AMGEN'S CARDIOVASCULAR CLINICAL TRIALS

*Learn About Active Studies*

**AMGEN**<sup>®</sup>  
Cardiovascular

Heart Failure



Atherosclerotic  
Cardiovascular Disease  
(ASCVD)



Scan  
to explore  
AMGEN pipeline



Scan  
to become an  
investigator site



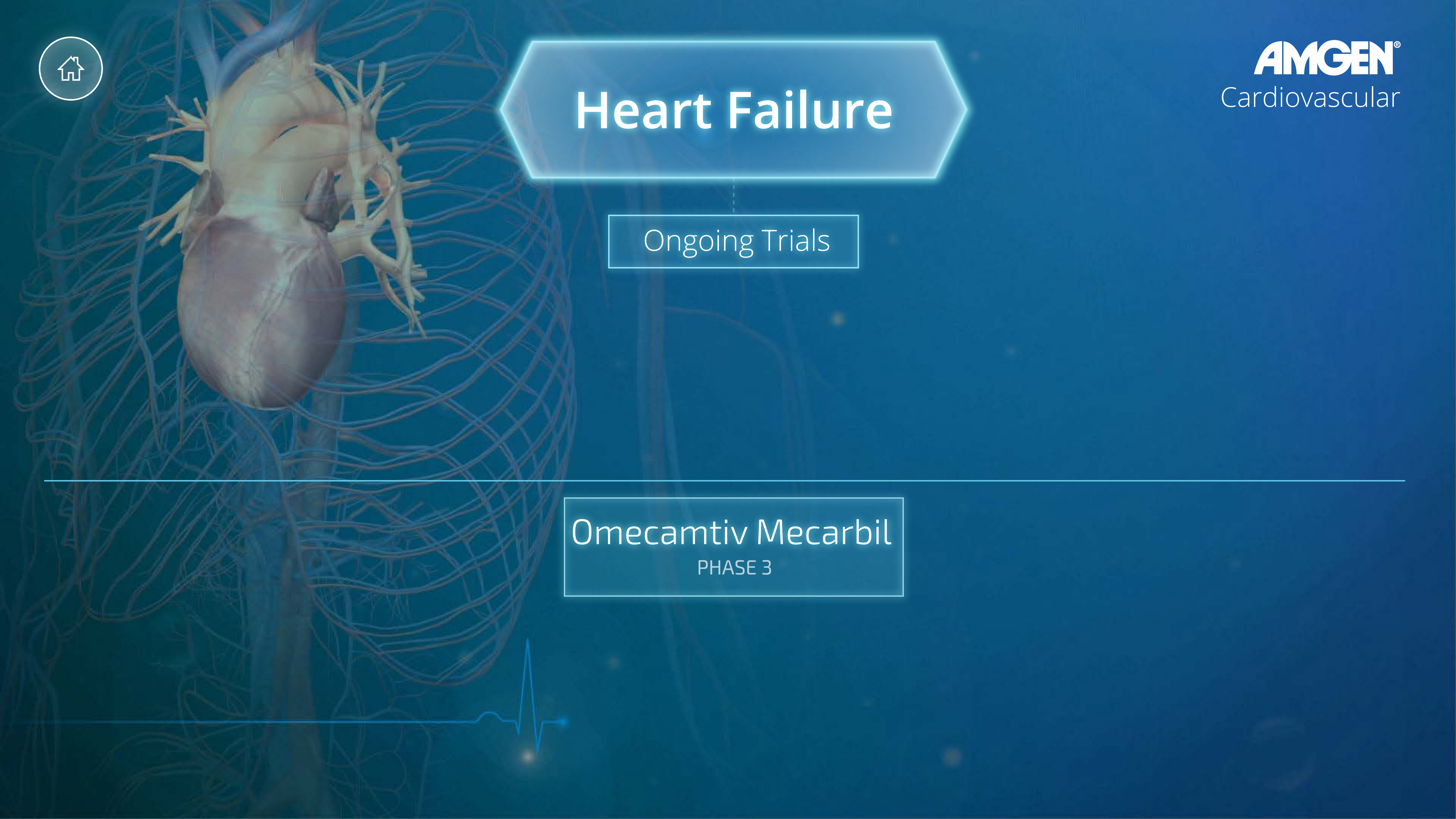




# Heart Failure

Ongoing Trials

Omecamtiv Mecarbil  
PHASE 3







# Heart Failure

## Omecamtiv Mecarbil

PHASE 3<sup>1</sup>

- Selective activator of cardiac myosin under investigation for the treatment of chronic heart failure<sup>2,3</sup>

Being developed by Amgen in collaboration with Cytokinetics, Inc. and in collaboration with Servier for certain territories.

1. Clinical Trials Website. NCT02929329. <https://clinicaltrials.gov/ct2/show/NCT02929329>. Updated May 30, 2019. Accessed February 10, 2020.
2. Cardiovascular Pipeline. Amgen Pipeline Website. [www.amgenpipeline.com/pipeline](http://www.amgenpipeline.com/pipeline). Updated April 30, 2019. Accessed February 10, 2020.
3. Malik FI, et al. *Science*. 2011;331:1439-1443.

### **GALACTIC-HF**

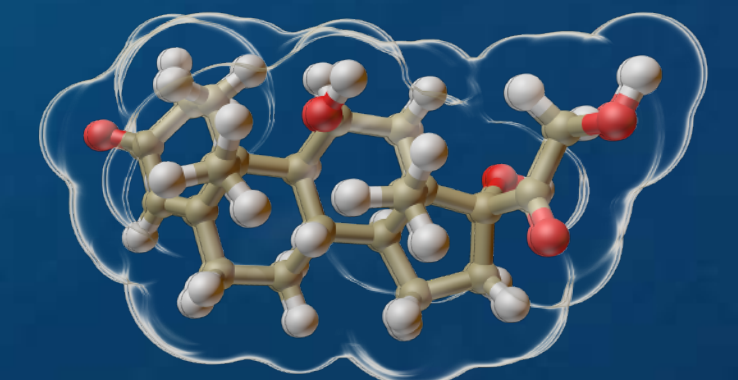
Global Approach to Lowering Adverse Cardiac Outcomes Through Improving Contractility in Heart Failure

### Ongoing Trials

### **METEORIC-HF**

Multicenter Exercise Tolerance Evaluation of Omecamtiv Mecarbil Related to Increased Contractility in Heart Failure

small molecule







# Heart Failure

Ongoing Trials

Omecamtiv Mecarbil  
PHASE 3



## Omecamtiv Mecarbil Phase 3 Study



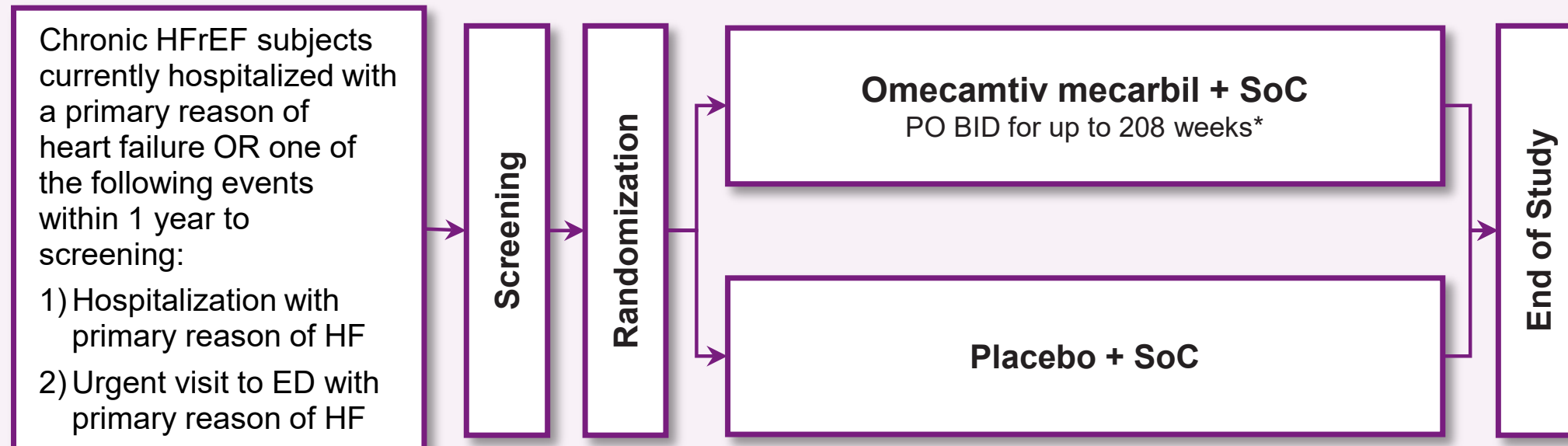
# Global Approach to Lowering Adverse Cardiac Outcomes Through Improving Contractility in Heart Failure

Amgen Clinical Study: 20110203

NCT Clinical Study: 02929329

**A Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Assess the Efficacy and Safety of Omecamtiv Mecarbil on Mortality and Morbidity in Subjects With Chronic Heart Failure With Reduced Ejection Fraction**

### PHASE 3 STUDY DESIGN:



BID = twice a day; ED = emergency department; HF = heart failure; HFrEF = heart failure with reduced ejection fraction; PO = orally; SoC = standard of care.

\*Dose level determined by periodic blood testing.

### STUDY PURPOSE:

To determine if treatment with omecamtiv mecarbil when added to standard of care (SoC) is well tolerated and superior to placebo and SoC in reducing the risk of cardiovascular (CV) death or heart failure (HF) events in subjects with chronic HF with reduced ejection fraction

### PRIMARY ENDPOINT:

- Time to CV death or first HF event

### SECONDARY ENDPOINTS:

- Time to CV death
- Changes in Kansas City Cardiomyopathy Questionnaire Total Symptom Score from baseline to week 24
- Time to first HF hospitalization
- Time to all-cause death

### OTHER OUTCOME MEASURES:

- Incidence of reported adverse events
- Incidence of reported serious adverse events of ventricular arrhythmias requiring treatment
- Incidence of positively adjudicated major cardiac ischemic events

### KEY INCLUSION CRITERIA:

- Men or women aged  $\geq 18$  to  $\leq 85$  years, with informed consent
- History of chronic HF (defined as requiring treatment for HF for a minimum of 30 days before randomization)
- Left ventricular ejection fraction  $\leq 35\%$  per subject's most recent medical record, within 12 months prior to screening
- New York Heart Association class II–IV at the most recent screening assessment
- Managed with HF SoC therapies consistent with regional clinical practice guidelines according to the investigator's judgment of subject's clinical status
- Current hospitalization with a primary reason of heart failure OR one of the following events within 1 year to screening:
  - 1) Hospitalization with primary reason of HF
  - 2) Urgent visit to emergency department with primary reason of HF
- Elevated B-type natriuretic peptide (BNP) or N-terminal pro-BNP

### KEY EXCLUSION CRITERIA:

- Currently receiving treatment in another investigational device or drug study, or  $< 30$  days since ending treatment on another investigational device or drug study(ies). Participation in other investigational procedures while participating in this study is not allowed
- Malignancy within 5 years prior to randomization with the following exceptions: localized basal or squamous cell carcinoma of the skin, cervical intraepithelial neoplasia, stage 1 prostate carcinoma, or breast ductal carcinoma in situ
- Known sensitivity to any of the products or components to be administered during testing
- Other exclusion criteria may apply

### ADDITIONAL INFORMATION:

[www.amgen.com](http://www.amgen.com) (Protocol Number: 20110203)

[www.clinicaltrials.gov](http://www.clinicaltrials.gov) (Identifier: 02929329)

Omecamtiv mecarbil is being investigated by Amgen in collaboration with Cytokinetics and Servier. Efficacy and safety have not been established.







# Heart Failure

Ongoing Trials

Omecamtiv Mecarbil  
PHASE 3



## Omecamtiv Mecarbil Phase 3 Study



### Multicenter Exercise Tolerance Evaluation of *Omecamtiv Mecarbil* Related to Increased Contractility in Heart Failure

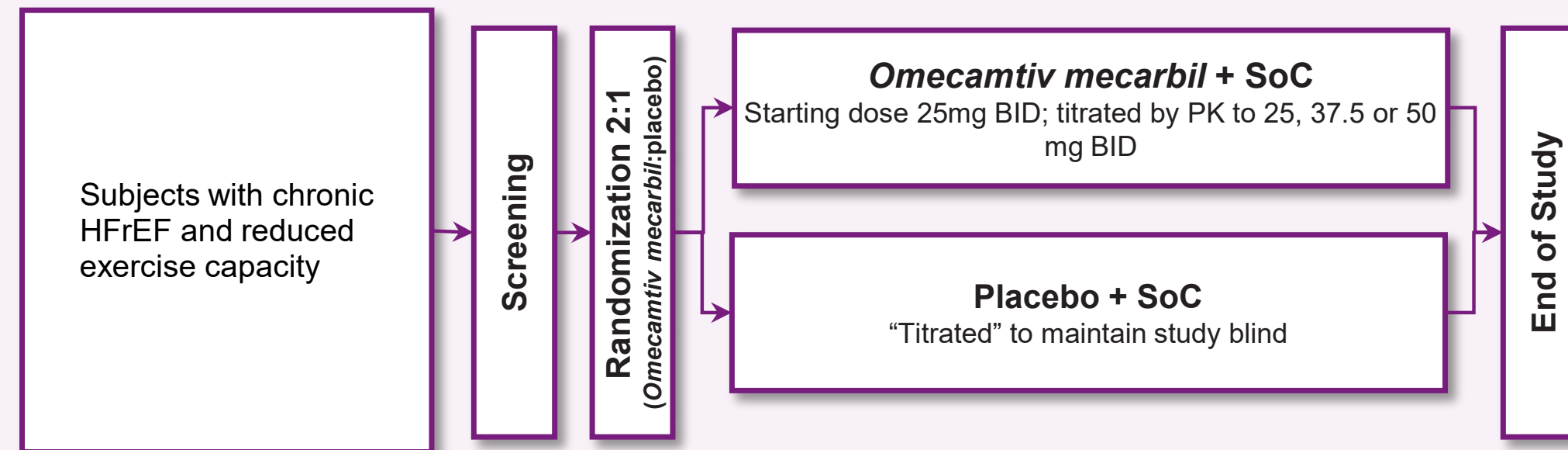
Study to Assess the Effect of *Omecamtiv Mecarbil* on Exercise Capacity in Subjects With Heart Failure

Cytokinetics Clinical Study: CY 1031

NCT Clinical Study: 03759392

**A Double-Blind, Randomized, Placebo-controlled, Multicenter Study to Assess the Effect of *Omecamtiv Mecarbil* on Exercise Capacity in Subjects with Heart Failure With Reduced Ejection Fraction and Decreased Exercise Tolerance**

#### PHASE 3 STUDY DESIGN:



Soc = Standard of Care

#### STUDY PURPOSE:

To evaluate the effect of treatment of *omecamtiv mecarbil* compared with placebo on exercise capacity as determined by cardiopulmonary exercise testing (CPET) following 20 weeks of treatment with *omecamtiv mecarbil* or placebo

#### PRIMARY ENDPOINT:

- Change in peak oxygen uptake (VO<sub>2</sub>) CPET from baseline to week 20

#### SECONDARY ENDPOINTS:

- Change in exercise capacity, as measured by the change in total workload during CPET from baseline to week 20
- Change in ventilatory efficiency, as measured by the change in Ventilation (VE)/Carbon dioxide output (VCO<sub>2</sub>) slope during CPET from baseline to Week 20
- Change in the average daily activity units measured over a 2-week period from baseline (Week -2 to Day 1) to Week 18-20

#### KEY INCLUSION CRITERIA:

- Men or women aged ≥ 18 to ≤ 85 years of age
- History of chronic HF, defined as requiring continuous treatment with medications for HF for a minimum of 3 months before screening
- New York Heart Association (NYHA) class II or III at screening
- Left ventricular ejection fraction ≤ 35%
- On maximally tolerated HF SoC therapies consistent with regional clinical practice guidelines, if not contraindicated and according to investigator judgement of the subject's clinical status. Beta blocker dose must be stable for 30 days prior to randomization
- N-terminal (NT)-proBNP level ≥ 200pg/mL
- Peak VO<sub>2</sub> ≤ 75% of the predicted normal value with respiratory exchange ratio (RER) ≥ 1.05 on a screening CPET, confirmed by a CPET core laboratory

#### KEY EXCLUSION CRITERIA:

- Paroxysmal atrial fibrillation or flutter documented within the previous 6 months, direct-current (DC) cardioversion or ablation procedure for atrial fibrillation within 6 months, or plan to attempt to restore sinus rhythm within 6 months of randomization. Subjects with persistent atrial fibrillation and no sinus rhythm documented in the prior 6 months are permitted.
- Ongoing or planned enrollment in cardiac rehabilitation
- Major medical event or procedure within 3 months prior to randomization, including: hospitalization, surgery, renal replacement therapy or cardiac procedure. This includes episodes of decompensated HF that require IV HF treatment.
- Chronotropic incompetence (including inadequate pacemaker rate response) during CPET at screening, defined as a maximum heart rate <60% of the maximum predicted heart rate
- Other exclusion criteria may apply

#### ADDITIONAL INFORMATION:

[www.amgentrials.com](http://www.amgentrials.com) (Study ID: CY 1031)

[www.clinicaltrials.gov](http://www.clinicaltrials.gov) (Identifier: 03759392)

Amgen, Cytokinetics, and Servier. News Release; February 21, 2019.

Omecamtiv mecarbil is being investigated by Amgen in collaboration with Cytokinetics and Servier. Efficacy and safety have not been established.







# Atherosclerotic Cardiovascular Disease (ASCVD)

Dyslipidemia

Evolocumab

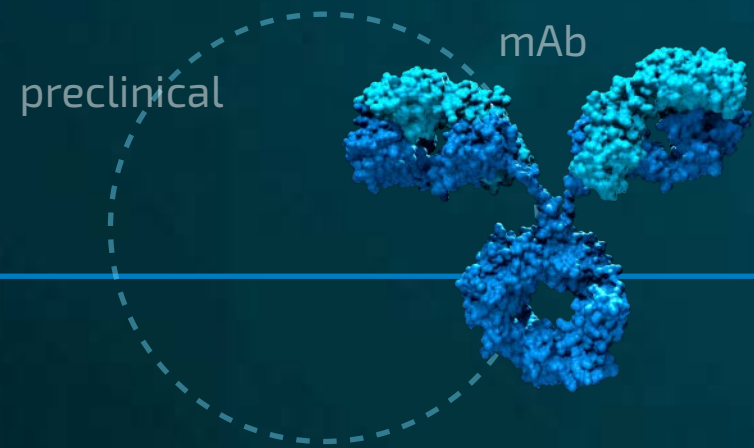
AMG 890  
Lp(a) Inhibitor  
PHASE 1

Ongoing Trials

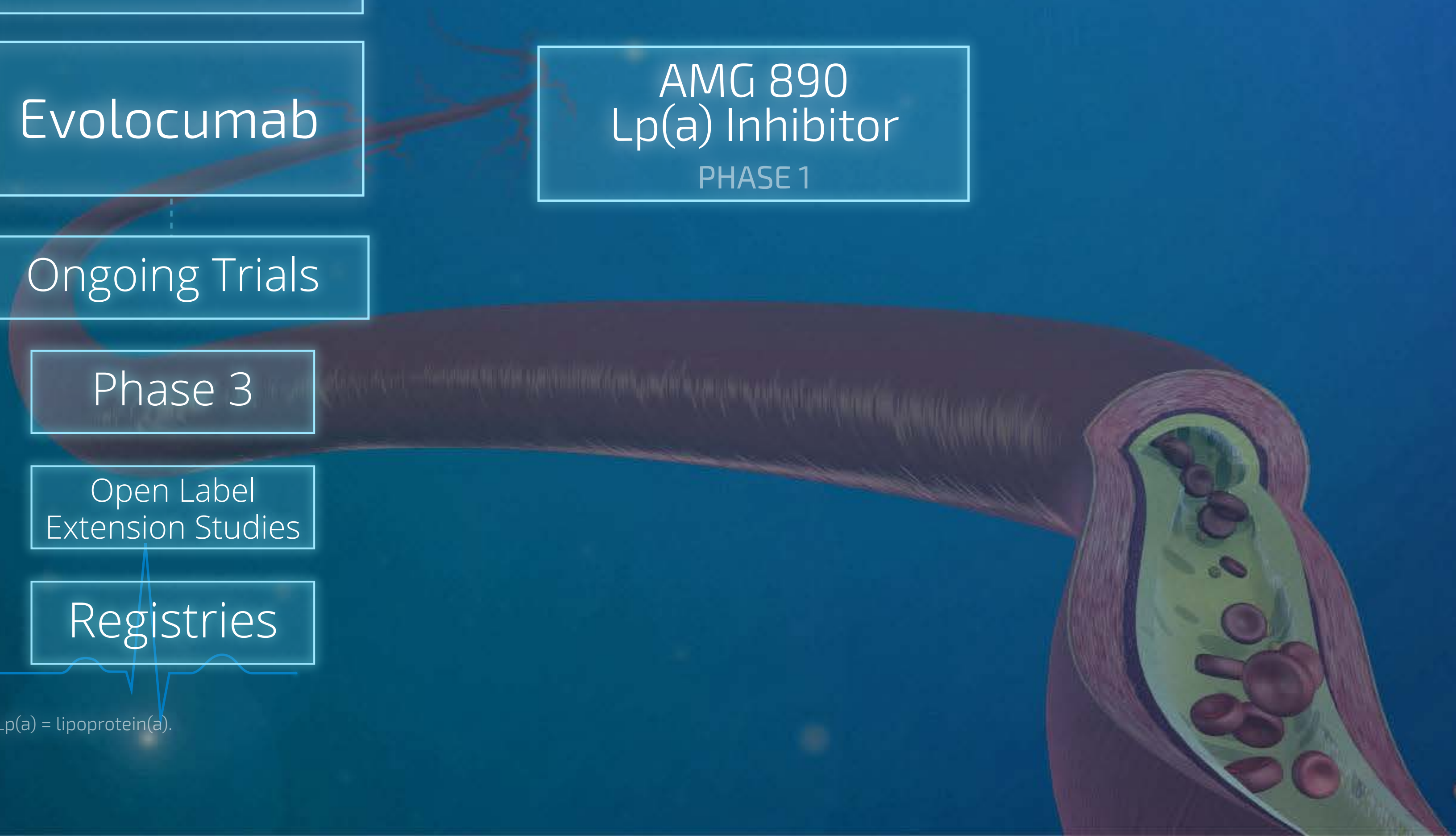
Phase 3

Open Label  
Extension Studies

Registries



mAb = monoclonal antibody; Lp(a) = lipoprotein(a).







# Atherosclerotic Cardiovascular Disease (ASCVD)

## Clinical Study Program

### Evolocumab Investigational Phase 3 & 4 Trials

#### HAUSER-RCT

Assessing Efficacy, Safety and Tolerability of PCSK9 Inhibition in Pediatric Subjects With Genetic LDL Disorders

#### HoFH INDIAN STUDY

(Phase 4)  
Safety and Tolerability of Evolocumab in Indian Subjects With Homozygous Familial Hypercholesterolemia

#### EVOLOCUMAB STUDY IN CHINESE PATIENTS

Safety and Efficacy of Evolocumab in Addition to Optimal Stable Background Statin Therapy in Chinese Subjects With Primary Hypercholesterolemia and Mixed Dyslipidemia

#### HUYGENS

High-Resolution Assessment of Coronary Plaques in a Global Evolocumab Randomized Study

#### VESALIUS-CV

Effect of Evolocumab in Patients at High Cardiovascular Risk Without Prior Myocardial Infarction or Stroke

## Registries

EU

#### EVOLOCUMAB PREGNANCY EXPOSURE REGISTRY:

An OTIS Pregnancy Surveillance Study

#### MOTHER TO BABY EVOLOCUMAB PREGNANCY EXPOSURE REGISTRY:

An OTIS Pregnancy Surveillance Study

US

#### GOULD

Getting to an Improved Understanding of LDL-C and Dyslipidemia Management: A Registry of High Cardiovascular Risk Subjects in the U.S.

#### cvMOBIUS

Cardiovascular Multidimensional Observational Investigation of the Use of PCSK9 Inhibitors

#### HEYMANS

Chart Review of Evolocumab in Subjects With Hyperlipidaemia

## Evolocumab Open Label Extension Studies

#### FOURIER OLE

Further Cardiovascular Outcomes Research With PCSK9 Inhibition in Subjects With Elevated Risk Open-Label Extension

#### HAUSER OLE

Open Label Study to Evaluate Safety, Tolerability and Efficacy of Evolocumab in Pediatric Subjects With Heterozygous Familial Hypercholesterolemia or Homozygous Familial Hypercholesterolemia





# Atherosclerotic Cardiovascular Disease (ASCVD)

Dyslipidemia

Evolocumab

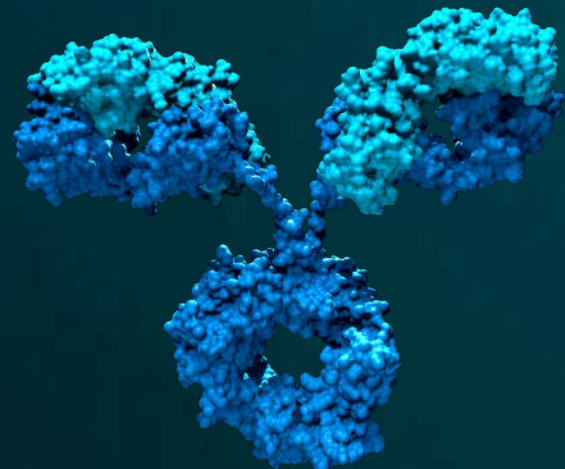
- Ongoing Phase 3 & 4 and Open Label Extension clinical development<sup>1,2</sup>
- Evolocumab is a human monoclonal IgG2 directed against human PCSK9<sup>3</sup>

PCSK9 = proprotein convertase subtilisin/kexin type 9

1. Clinical Trials Website. [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Accessed February 10, 2020.
2. Cardiovascular Pipeline. Amgen Pipeline Website. [www.amgenpipeline.com/pipeline](http://www.amgenpipeline.com/pipeline). Updated April 30, 2019. Accessed February 10, 2020.
3. Langslet G, et al. *Expert Rev Cardiovasc Ther*. 2015;13:477-488.

Ongoing Trials

mAb







Evolocumab

PHASE 3

Ongoing Trials

# Atherosclerotic Cardiovascular Disease (ASCVD)

Dyslipidemia



## Investigational trial for evolocumab in pediatric subjects

# HAUSER

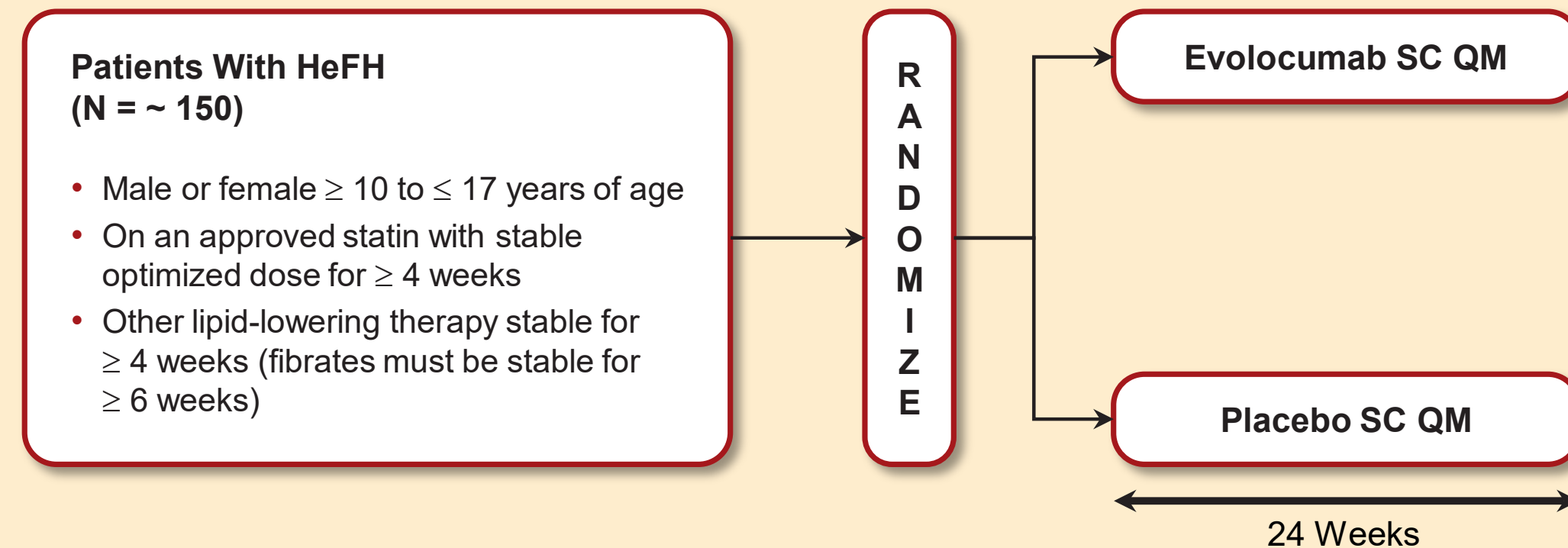
## Trial Assessing Efficacy, Safety and Tolerability of PCSK9 Inhibition in Pediatric Subjects With Genetic LDL Disorders (HAUSER-RCT)

Amgen Clinical Study: 20120123

NCT Clinical Study: 02392559

**Double-blind, Randomized, Multicenter, Placebo-Controlled Study to Characterize the Efficacy, Safety, and Tolerability of 24 Weeks of Evolocumab for LDL-C Reduction in Pediatric Subjects 10 to 17 Years of Age With HeFH**

### PHASE 3 STUDY DESIGN:



### PURPOSE:

A study to assess safety and efficacy of evolocumab (AMG-145) in pediatric subjects aged 10–17 years diagnosed with HeFH.

### PRIMARY ENDPOINT:

- Percentage change from baseline in LDL-C levels at week 24

### SECONDARY ENDPOINTS:

- Change from baseline in LDL-C levels at week 24
- Percentage change from baseline in ApoB levels at week 24
- Percentage change from baseline in TC:HDL-C ratio at week 24
- Change in ApoB:ApoA1 ratio at week 24
- Percentage change from baseline in non-HDL-C levels at week 24
- Mean percentage change from baseline in LDL-C levels at week 22 and 24

### KEY INCLUSION CRITERIA:

- Male or female  $\geq 10$  to  $\leq 17$  years of age (before 18th birthday)
- Diagnosis of HeFH
- On an approved statin with stable optimized dose for  $\geq 4$  weeks
- Other lipid-lowering therapy stable for  $\geq 4$  weeks (fibrates must be stable for  $\geq 6$  weeks)
- Fasting LDL-C  $\geq 130$  mg/dL (3.4 mmol/L)
- Fasting triglycerides  $\leq 400$  mg/dL (4.5 mmol/L)

### KEY EXCLUSION CRITERIA:

- Type 1 diabetes, or type 2 diabetes that is poorly controlled
- Uncontrolled hyperthyroidism or hypothyroidism
- CETP inhibitor in the last 12 months, or mipomersen or lomitapide in the last 5 months
- Previously received evolocumab or any other investigational therapy to inhibit PCSK9
- Lipid apheresis within the last 12 weeks prior to screening
- Homozygous familial hypercholesterolemia

### ADDITIONAL INFORMATION:

[www.amgentrials.com](http://www.amgentrials.com) (Protocol Number: 20120123)

[www.clinicaltrials.gov](http://www.clinicaltrials.gov) (Identifier: NCT02392559)

ApoA1 = apolipoprotein A1; ApoB = apolipoprotein B; CETP = cholesterylester transfer protein; HDL-C = high-density lipoprotein-cholesterol; HeFH = heterozygous familial hypercholesterolemia; LDL = low-density lipoprotein; LDL-C = LDL-cholesterol; PCSK9 = proprotein convertase subtilisin/kexin type 9; QM = once monthly; SC = subcutaneous; TC = total cholesterol.





Evolocumab  
PHASE 3  
Ongoing Trials

Atherosclerotic  
Cardiovascular Disease  
(ASCVD)  
Dyslipidemia



Evolocumab Intracoronary Imaging Study



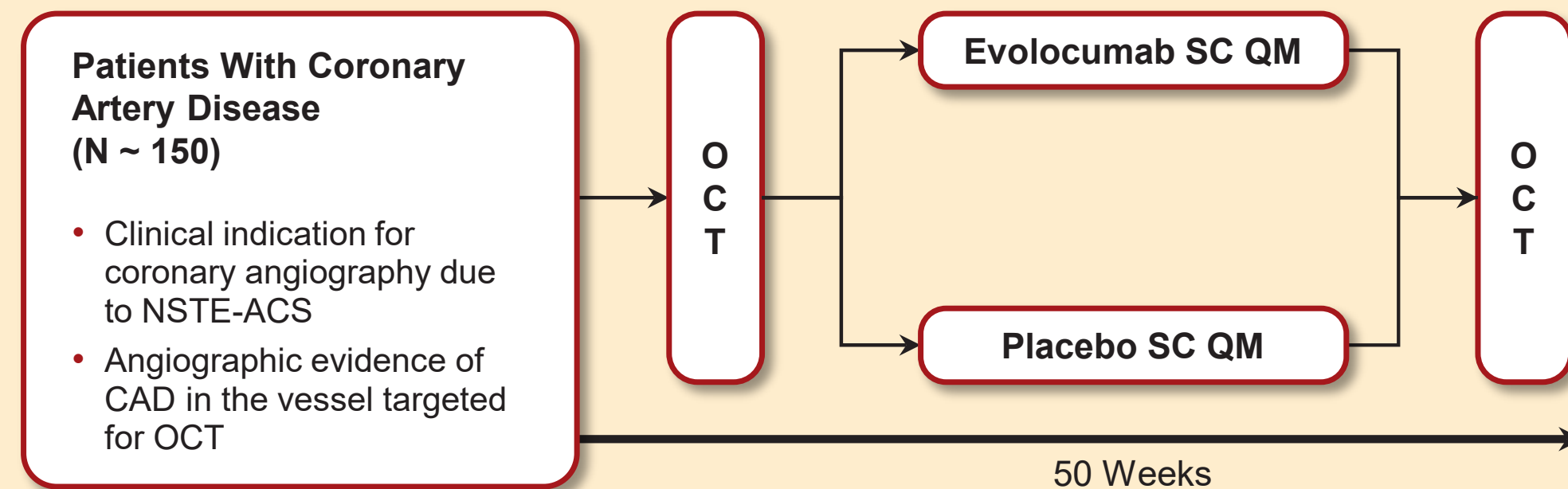
High-Resolution Assessment of Coronary Plaques  
in a Global Evolocumab Randomized Study

Amgen Clinical Study: 20160184

NCT Clinical Study: 03570697

A double-blind, placebo-controlled, multicenter, randomized study evaluating the effect of evolocumab on coronary atherosclerotic plaques as assessed by OCT in subjects with an NSTE-ACS who are taking maximally tolerated statin therapy

PHASE 3 STUDY DESIGN:



STUDY PURPOSE:

Evaluate the effect of evolocumab on fibrous cap thickness in subjects with NSTE-ACS who are taking maximally tolerated statin therapy

PRIMARY OUTCOME MEASURE:

- Absolute change in minimum FCT in a matched segment of artery as determined by OCT from baseline to week 50

SECONDARY OUTCOME MEASURES:\*

- Percent change in minimum FCT in a matched segment of artery at week 50
- Absolute change in mean minimum FCT for all images assessed at week 50
- Absolute change in the maximum lipid arc in a matched segment of artery at week 50
- Absolute change in minimum FCT, maximum lipid arc, and lipid core length in lipid rich plaques† at week 50

KEY INCLUSION CRITERIA:‡

- Clinical indication for coronary angiography due NSTE-ACS
- Angiographic evidence of CAD in the vessel targeted for OCT
- Eligible LDL-C level based on current statin use
- On maximally tolerated statin therapy in accordance with local guidelines

KEY EXCLUSION CRITERIA:‡

- STEMI or left bundle branch block
- ACS likely to be caused by a non-atherosclerotic process
- Any cardiac surgery within 6 weeks prior to screening
- TG ≥ 400 mg/dL (4.5 mmol/L)
- eGFR < 30 mL/min/1.73m<sup>2</sup>
- Intolerant to statins

ADDITIONAL INFORMATION:

[www.amgen.com](http://www.amgen.com) (Protocol Number: 20160184)

[www.clinicaltrials.gov](http://www.clinicaltrials.gov) (Identifier: 03570697)

\*Note: Not all secondary endpoints listed. Additional exploratory endpoints based on IVUS. †There is no universal definition of a lipid-rich plaque as defined in the study protocol. ‡Note: Not inclusive of all criteria.  
CAD = coronary artery disease; eGFR = estimated glomerular filtration rate; FCT = fibrous cap thickness; IVUS = intravascular ultrasound; LDL-C = low-density lipoprotein cholesterol; NSTE-ACS = non-ST-elevation acute coronary syndrome;  
OCT = optical coherence tomography; QM = monthly; SC = subcutaneous; STEMI = ST-elevation myocardial infarction; TG = triglycerides.





Evolocumab

PHASE 3

Ongoing Trials

# Atherosclerotic Cardiovascular Disease (ASCVD)

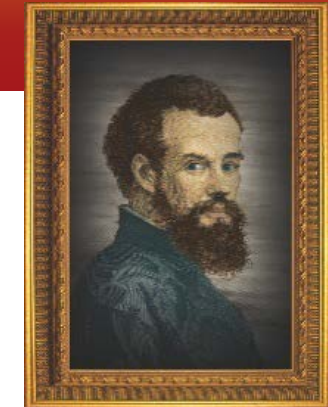
Dyslipidemia



Investigational trial for evolocumab in high risk patients

## Vesalius-cv

# Effect of EVolocumab in PatiEntS at High CArdiovascuLar Risk WithoUt Prior Myocardial Infarction or Stroke

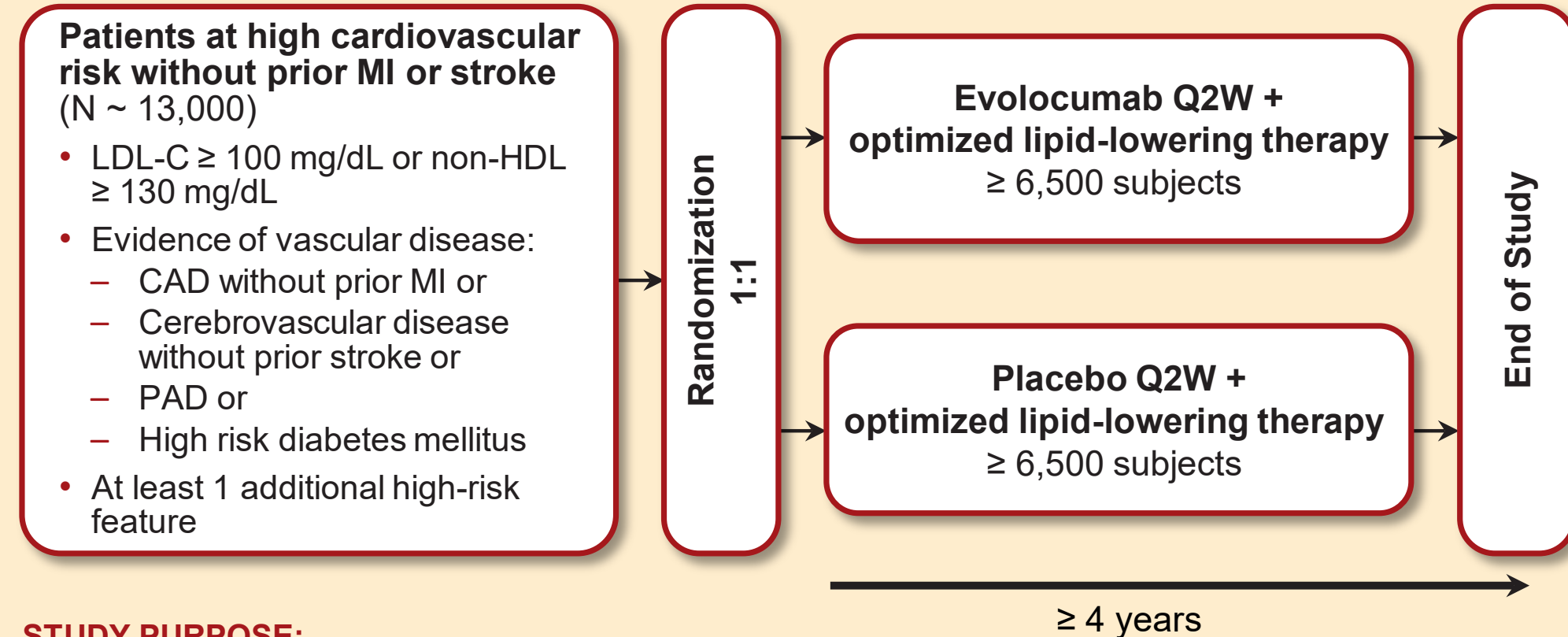


Amgen Clinical Study: 20170625

NCT Clinical Study: 03872401

**A Double-blind, Randomized, Placebo-controlled, Multicenter Study to Evaluate the Impact of Evolocumab on Major Cardiovascular Events in Patients at High Cardiovascular Risk Without Prior Myocardial Infarction or Stroke**

### PHASE 3 STUDY DESIGN:



### STUDY PURPOSE:

Assess the effect of lowering LDL-C with evolocumab on major cardiovascular events in subjects without a prior MI or stroke who are at high risk for a first cardiovascular event

### PRIMARY OUTCOME MEASURES\* (Time to):

- CHD death, MI, or ischemic stroke, whichever occurs first
- CHD death, MI, ischemic stroke, or any ischemia-driven arterial revascularization, whichever occurs first

### SECONDARY OUTCOME MEASURES\* (Time to):

- MI, ischemic stroke, or any ischemia-driven arterial revascularization
- CHD death, MI, or any ischemia-driven arterial revascularization
- CV death, MI, or stroke
- MI
- Any ischemia-driven arterial revascularization
- CHD death
- CV death
- All-cause death
- Ischemic stroke

### KEY INCLUSION CRITERIA: (All 4 needed)

- Adult subjects ≥ 50 (men) or ≥ 55 (women) to < 80 years of age (either sex)
- LDL-C ≥ 100 mg/dL (≥ 2.6 mmol/L) or non-HDL-C ≥ 130 mg/dL (≥ 3.4 mmol/L) at screening, after ≥ 4 weeks of optimized lipid-lowering therapy
- Evidence of at least one of the following at screening:
  - Significant CAD
  - Significant atherosclerotic cerebrovascular disease
  - Significant PAD
  - Diabetes mellitus
- At least 1 high-risk feature

### KEY EXCLUSION CRITERIA†:

- MI or stroke prior to randomization
- CABG < 3 months prior to screening
- Uncontrolled hypertension (sitting systolic BP > 180 mmHg or diastolic BP > 110 mmHg)
- Fasting triglycerides ≥ 500 mg/dL (5.7 mmol/L)
- Last measured left ventricular ejection fraction < 30% or NYHA Functional Class III/IV

### ADDITIONAL INFORMATION:

www.amgentrials.com (Protocol Number: 20170625)    www.clinicaltrials.gov (Identifier: NCT03872401)

\*May not be inclusive of all study details. †For adults at high cardiovascular risk without past MI or stroke and receiving optimized lipid-lowering therapy.

BP = blood pressure; CABG = coronary artery bypass graft; CAD = coronary artery disease; CHD = coronary heart disease; CV = cardiovascular; HDL-C = high-density lipoprotein cholesterol; LDL-C = low-density lipoprotein cholesterol; MI = myocardial infarction; NYHA = New York Heart Association; PAD = peripheral arterial disease; Q2W = every 2 weeks.





Evolocumab

PHASE 4

Ongoing Trials

Atherosclerotic Cardiovascular Disease (ASCVD)

Dyslipidemia

AMGEN Cardiovascular

## Evolocumab HoFH Study in India

# Safety and Tolerability of Evolocumab in Indian Subjects With Homozygous Familial Hypercholesterolemia

Amgen Clinical Study: 20170199

NCT Clinical Study: 03403374

**A Multicenter, Open-Label, Single-arm, Study to Evaluate Safety and Tolerability of Evolocumab in Patients With Homozygous Familial Hypercholesterolemia (HoFH) in India**

### PHASE 4 STUDY DESIGN:

#### Patients With HoFH (N ~ 30)

- Male or female  $\geq 12$  to  $\leq 80$  years of age
- Diagnosis of HoFH based on LDL-C, familial history and xanthoma
- On lipid-lowering therapy stable for 4 weeks

**Evolocumab 420 mg SC QM + Standard of Care\***

12 Weeks

### PRIMARY OUTCOME MEASURE:

- Number of participants with treatment related adverse events (week 12)

### SECONDARY OUTCOME MEASURES:

- Change in LDL-C (week 12)
- Change in ApoB (week 12)
- Change in Lp(a) (week 12)

### KEY INCLUSION CRITERIA†:

- Male or female  $\geq 12$  to  $\leq 80$  years of age
- Diagnosis of HoFH based on LDL-C, familial history and xanthoma
- On a low-fat diet and receiving background lipid-lowering therapy
- Lipid-lowering therapy stable for 4 weeks prior to screening
- Fasting LDL-C at screening  $> 130$  mg/dL (3.4 mmol/L)
- Fasting TG  $\leq 400$  mg/dL (4.5 mmol/L)

### KEY EXCLUSION CRITERIA†:

- Use of mipomersen or lomitapide within 6 months of screening
- Known active infection or major hematologic, renal, metabolic, GI, hepatic, or endocrine dysfunction
- Currently receiving treatment in another investigational device or drug study, or less than 30 days since ending treatment on another investigational device or drug study(ies)

### STUDY PURPOSE:

Describe the safety and tolerability of evolocumab in subjects with HoFH in India

### ADDITIONAL INFORMATION:

[www.amgentrials.com](http://www.amgentrials.com) (Protocol Number: 20170199)

[www.clinicaltrials.gov](http://www.clinicaltrials.gov) (Identifier: 03403374)

\*Note: Apheresis subjects will receive evolocumab SC; subjects on apheresis may initiate 420 mg SC Q2W to correspond with their apheresis schedule to correspond with apheresis schedule. †Note: Not inclusive of all criteria. ApoB = apolipoprotein B; HoFH = homozygous familial hypercholesterolemia; LDL-C = low-density lipoprotein cholesterol; Lp(a) = lipoprotein(a); QM = monthly; SC = subcutaneous; TG = triglycerides.





Evolocumab  
PHASE 3  
Ongoing Trials

# Atherosclerotic Cardiovascular Disease (ASCVD)

Dyslipidemia



## Evolocumab Study in Chinese Patients

**HUA TUO**  
**华佗**

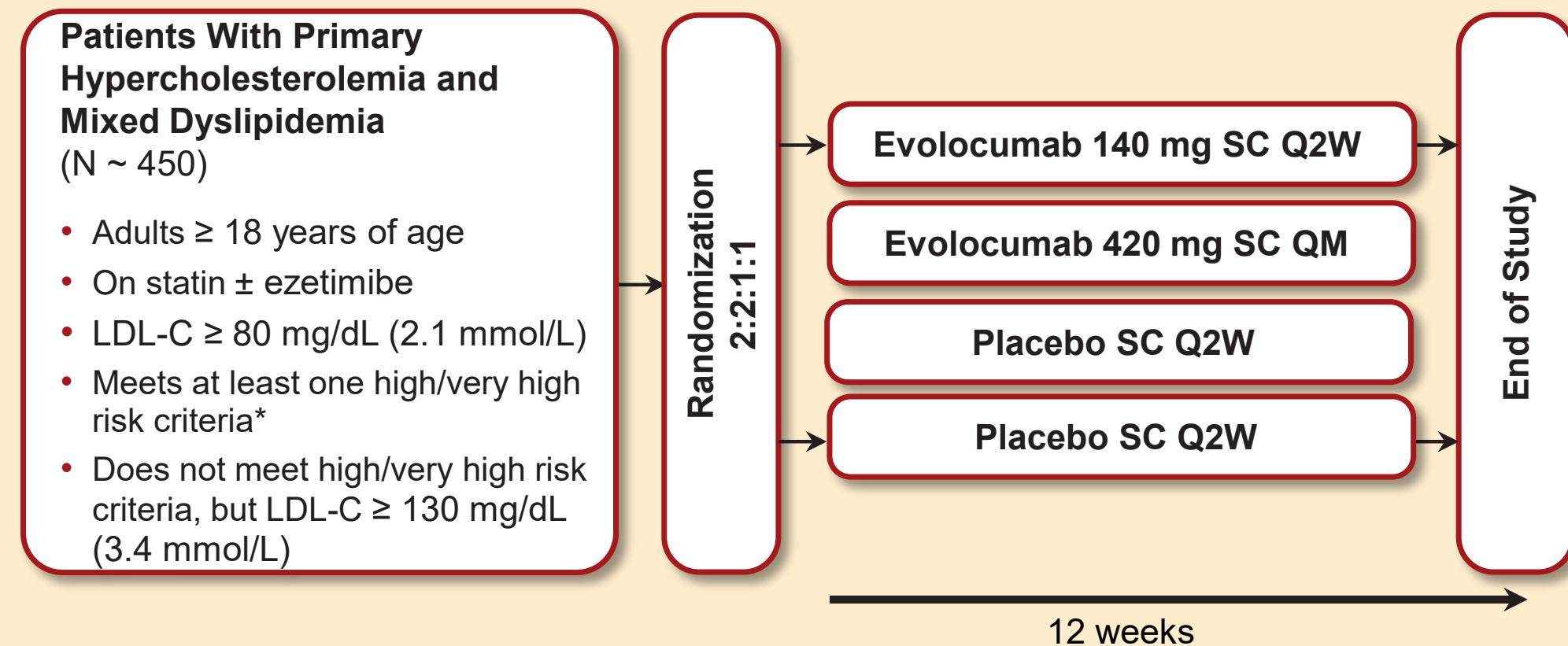
### Safety and Efficacy of Evolocumab in Addition to Optimal Stable Background Statin Therapy in Chinese Subjects With Primary Hypercholesterolemia and Mixed Dyslipidemia

Amgen Clinical Study: 20150172

NCT Clinical Study: 03433755

**A Double-blind, Randomized, Placebo-controlled, Multicenter Study to Evaluate Safety and Efficacy of Evolocumab in Addition to Optimal Stable Background Therapy in Chinese Subjects With Primary Hypercholesterolemia and Mixed Dyslipidemia**

**PHASE 3 STUDY DESIGN:**



**STUDY PURPOSE:**

Learn more about evolocumab in Chinese people with primary hypercholesterolemia and mixed dyslipidemia

**PRIMARY OUTCOME MEASURES:**

- Mean percent change from baseline in LDL-C at weeks 10 and 12
- Percent change from baseline in LDL-C at week 12

**SECONDARY OUTCOME MEASURES†:**

- LDL-C
- Non-HDL-C
- ApoB
- Total cholesterol
- Target LDL-C < 70 mg/dL (1.8 mmol/L)
- LDL-C response
- Lp(a)
- Triglycerides
- HDL-C
- VLDL-C

**KEY INCLUSION CRITERIA‡:**

- Adults ≥ 18 years of age
- On statin, ± ezetimibe
- LDL-C ≥ 80 mg/dL (2.1 mmol/L)
- Subjects meets ≥ 1 high/very high CV risk criteria:
  - Hx of CAD
  - Hx of ischemic stroke
  - Diagnosis of PAD
  - eGFR ≥ 30 – 60 mL min/1.73m<sup>2</sup>
  - Diagnosis of T2DM
  - Presence of ≥ 3 of the following risk factors: ≥ 45 years (male), ≥ 55 years (female), HTN, smoking, family hx of premature CVD, HDL-C < 40 mg/dL, obese
- Subject does not meet high/very high risk criteria, but LDL-C ≥ 130 mg/dL (3.4 mmol/L)

**KEY EXCLUSION CRITERIA†:**

- MI, unstable angina, PCI, CABG or stroke < 3 months prior to randomization
- Last measured LVEF < 30% or NYHA Functional Class III/IV
- Uncontrolled HTN (defined as sitting SBP > 180 mmHg or DBP > 100 mmHg)
- T1DM, NODM ( HbA1c ≥ 6.5% or FPG ≥ 126 mg/dL) or poorly controlled (HbA1c ≥ 8.5%) T2DM

**ADDITIONAL INFORMATION:**

[www.amgentrials.com](http://www.amgentrials.com) (Protocol Number: 20150172)

[www.clinicaltrials.gov](http://www.clinicaltrials.gov) (Identifier: 03433755)

\*Hx of CAD, hx of ischemic stroke, diagnosis of PAD, eGFR ≥ 30 – 60 mL min/1.73m<sup>2</sup>, diagnosis of T2DM, presence of ≥ 3 of the following risk factors: ≥ 45 years (male), ≥ 55 years (female), HTN, smoking, family hx of premature CVD, HDL-C < 40 mg/dL, obese. †Not all secondary measures listed.

‡Not inclusive of all criteria

ApoB = apolipoprotein B; CABG = coronary artery bypass graft; CVD = cardiovascular disease; DM = diabetes mellitus; FPG = fasting plasma glucose; HDL-C = high-density lipoprotein cholesterol; HTN = hypertension; LDL-C = low-density lipoprotein cholesterol; Lp(a) = lipoprotein (a); LVEF = left ventricular ejection fraction; MI = myocardial infarction; NODM = new onset diabetes mellitus; NYHA = New York Heart Association; PAD = peripheral arterial disease; PCI = percutaneous coronary intervention; Q2W= biweekly; QM = monthly; VLDL-C= very low-density lipoprotein cholesterol





Evolocumab

PHASE 3

Ongoing Trials

# Atherosclerotic Cardiovascular Disease (ASCVD)

Dyslipidemia



## Real World Effectiveness of PCSK9 Inhibitors Among Patients With a Recent ASCVD Event



# Cardiovascular Multidimensional Observational Investigation of the Use of PCSK9 Inhibitors

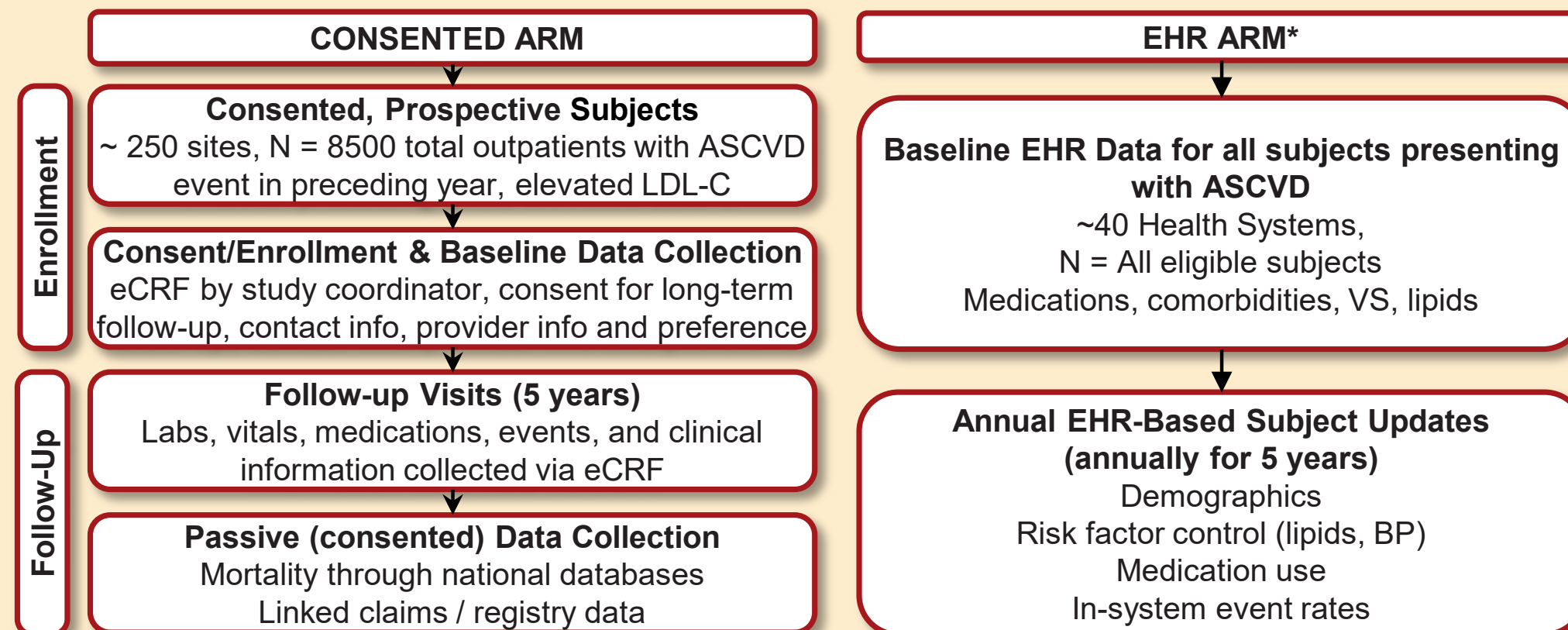
Amgen Clinical Study: 20180059

NCT Clinical Study: NCT04197453

### STUDY PURPOSE:

cvMOBIUS is a North American registry of patients with ASCVD aimed at understanding patterns of care in ASCVD while evaluating the real world effectiveness of PCSK9 inhibitors (PCSK9i).

### STUDY DESIGN:



\*Note: Sites must enroll subjects in consented arm in order to participate in the EHR-Arm.

### PRIMARY OBJECTIVE:

To evaluate the real-world effectiveness of PCSK9i's to reduce cardiovascular events in routine practice in a prospective cohort of adults presenting with a recent ASCVD event and/or revascularization procedure.

### KEY SECONDARY OBJECTIVE:

To understand the strengths and limitations of data harvested directly from electronic health record (EHR) systems as compared with prospectively collected information.

### PRIMARY OUTCOMES:

Composite of all-cause mortality, non-fatal MI, non-fatal IS

### CONSENTED ARM:

#### INCLUSION CRITERIA:

- Age  $\geq 40$  years with planned follow-up in the enrolling health system
- One or both of the following:
  - Hospitalization for a clinical ASCVD event: acute MI, UA, IS or CLI within 12 months of enrollment
  - Coronary or peripheral revascularization including percutaneous or surgical revascularization in the past 12 months
- One of the following:
  - Low-density lipoprotein (LDL)  $\geq 70$  mg/dL with no plans for immediate initiation or titration of statin therapy (Note: Subjects should not be enrolled into study during initiation/titration of statins until they have a stable LDL-C measurement  $> 4$  weeks after their last statin change and no immediate plans for future titration) –OR–
  - Newly started on PCSK9i after the index hospitalization/procedure and prior to enrollment (but no more than 6 months prior to enrollment) with pre-PCSK9i treatment LDL-C value available and measured within 6 months of starting PCSK9i and known background LLT any time prior to PCSK9i initiation
- One or both of the following:
  - The presence of an additional ASCVD event: prior history of MI, CVA, or symptomatic PAD

- One or more high-risk conditions: age  $\geq 65$  years old, HeFH, history of CABG, or PCI outside of the major event, DM, HTN, chronic renal insufficiency, current smoking, HF, or elevated Lp(a) ( $\geq 50$  mg/dL)
- Planned follow-up within the health system

#### KEY EXCLUSION CRITERIA\*:

- End stage renal disease (ESRD) or stage 5 chronic kidney disease (CKD)
  - Anticipated life expectancy less than 6 months
  - On a PCSK9i prior to their index event
- Note: Subjects with prior PCSK9i use occurring and ending before the 12-month period prior to enrollment and before the index ASCVD event will be considered for inclusion.

#### EHR ARM:

##### INCLUSION CRITERIA:

- Adults age  $\geq 40$  years of age
- Have at least 1 inpatient or outpatient diagnosis of clinical ASCVD within 12 months prior to enrollment including CHD, ischemic cerebrovascular disease, PAD, or prior coronary or peripheral revascularization

##### EXCLUSION CRITERIA:

- No exclusion criteria will be applied for the EHR arm

### ADDITIONAL INFORMATION:

www.amgentrials.com (Protocol Number: 20180059)

www.clinicaltrials.gov (Identifier: NCT04197453)

\*Not inclusive of all key exclusion criteria. Study Contacts: Eric Peterson, MD (Duke Clinical Research Institute), Ann Marie Navar, MD, PhD (Duke Clinical Research Institute). Study Email Contacts: cvMOBIUS@duke.edu. Consented Arm Questions: www.amgenmediainfo.com.

ASCVD = atherosclerotic cardiovascular disease; BP = blood pressure; CABG = coronary artery bypass grafting; CHD = coronary heart disease; CLI = critical limb ischemia; CVA = cerebrovascular accident; DM = diabetes mellitus; eCRF = electronic case report form; EHR = electronic health record; HeFH = heterozygous familial hypercholesterolemia; HF = heart failure; HTN = hypertension; IS = ischemic stroke; LDL-C = low-density lipoprotein cholesterol; LLT = lipid lowering therapy; Lp(a) = lipoprotein (a); MI = myocardial infarction; PAD = peripheral artery disease; PCI = percutaneous coronary intervention; PCSK9 = proprotein convertase subtilisin/kexin type 9; UA = unstable angina; VS = vital signs. Reference: www.clinicaltrials.gov (Identifier:04197453) and Data on File, Amgen;2019.





Evolocumab

Open Label Extension

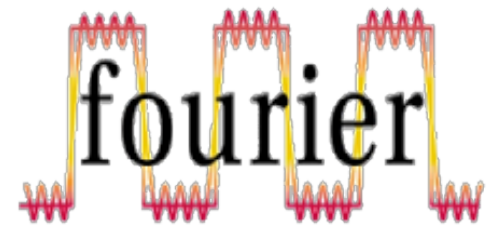
Ongoing Trials

# Atherosclerotic Cardiovascular Disease (ASCVD)

Dyslipidemia



## Evolocumab open label extension study



# Further Cardiovascular Outcomes Research With PCSK9 Inhibition in Subjects With Elevated Risk Open-Label Extension (FOURIER OLE)

Amgen Clinical Study: 20130295, 20160250

NCT Clinical Study: 02867813, 03080935



Two Multicenter, Open-label Extension (OLE), Single-Arm Studies to Assess Long-term Safety of Evolocumab Therapy in Patients With Clinically Evident Cardiovascular Disease

### PHASE 3 STUDY DESIGN:

**Patients With Hypercholesterolemia and History of Clinically Evident CVD**  
(N = 5,037 in US and Eastern Europe for Study 20130295)\*  
(N ~ 1,600 in Western Europe for Study 20160250)†

- Completed FOURIER (20110118) study
- Age ≥ 40 to ≤ 85 years

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**Evolocumab**  
140 mg Q2W or 420 mg QM,  
according to patient  
preference

~ 5 years

### PRIMARY ENDPOINT:

- Subject incidence of adverse events

### SECONDARY ENDPOINTS:

- Percent change in LDL-C from baseline to each yearly visit
- Achievement of LDL-C < 40 mg/dL (1.03 mmol/L) at each yearly visit

### KEY INCLUSION CRITERIA:

- Completed FOURIER (20110118) parent study while still receiving assigned investigational product
- Age ≥ 40 to ≤ 85 years

### KEY EXCLUSION CRITERIA:

- Permanent discontinuation of Investigational Product during FOURIER for any reason including an adverse event or serious adverse event

### PURPOSE:

This study will contribute to the evaluation of the primary clinical hypothesis that long-term exposure of evolocumab will be safe and well tolerated in subjects with clinically evident atherosclerotic cardiovascular disease (ASCVD).

### ADDITIONAL INFORMATION:

[www.amgentrials.com](http://www.amgentrials.com) (Protocol Numbers: 20130295, 20160250)

[www.clinicaltrials.gov](http://www.clinicaltrials.gov) (Identifiers: NCT02867813, NCT03080935)

CVD = cardiovascular disease; LDL-C = low-density lipoprotein cholesterol; PCSK9 = proprotein convertase subtilisin/kexin type 9; Q2W = once every 2 weeks; QM = once monthly.

\*Study 20130295 includes the United States, Czechia, Hungary, Poland, Russian Federation, Slovakia, and Ukraine.

†Study 20160250 includes the following European countries: Belgium, Denmark, France, Germany, Italy, Portugal, and Sweden.





Evolocumab

Open Label Extension

Ongoing Trials

# Atherosclerotic Cardiovascular Disease (ASCVD)

Dyslipidemia



## Evolocumab open label extension study in pediatric subjects

# HAUSER

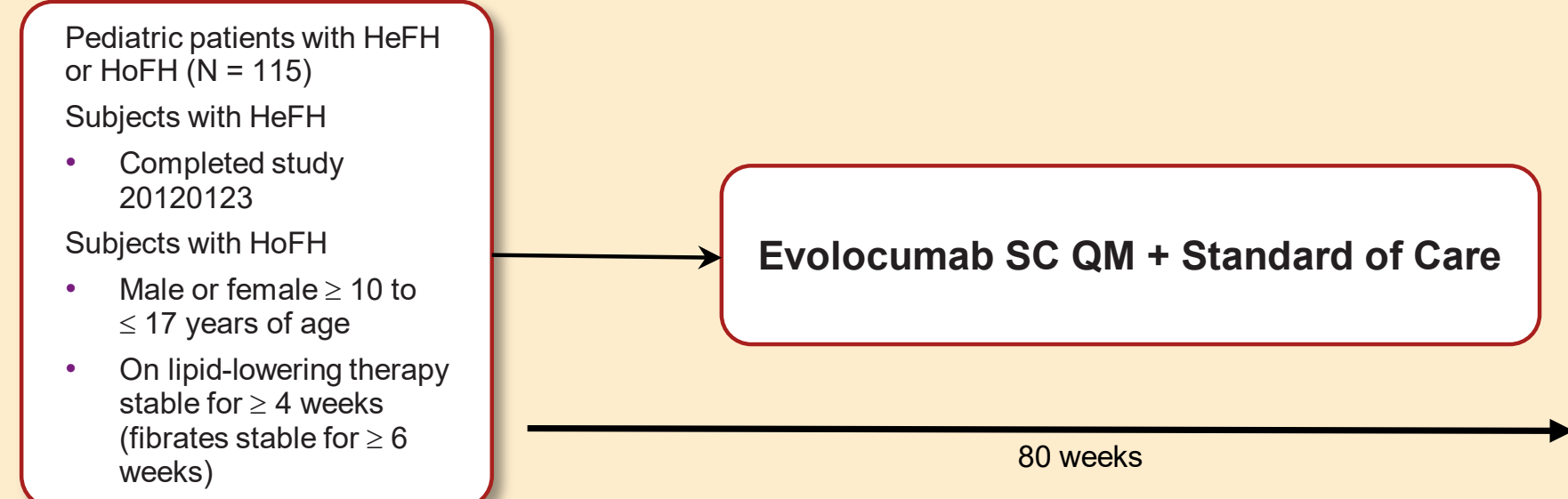
### Open Label Study to Evaluate Safety, Tolerability and Efficacy of Evolocumab in Pediatric Subjects With Heterozygous Familial Hypercholesterolemia or Homozygous Familial Hypercholesterolemia (HAUSER-OLE)

Amgen Clinical Study: 20120124

NCT Clinical Study: 02624869

**Open-label, Single-Arm, Multicenter Study to Evaluate the Safety, Tolerability and Efficacy of Evolocumab for LDL-C Reduction, as Add-on Diet and Lipid-lowering Therapy, in Pediatric Subjects From 10 to 17 Years of Age With Heterozygous Familial Hypercholesterolemia (HeFH) or Homozygous Familial Hypercholesterolemia (HoFH)**

#### PHASE 3 STUDY DESIGN:



#### STUDY PURPOSE:

To describe the safety and tolerability of 80 weeks of evolocumab (AMG 145) when added to standard of care in pediatric subjects 10 to 17 years of age with HeFH or HoFH.

#### PRIMARY OUTCOME MEASURES:

- Number of participants with treatment-related adverse events as assessed by Common Terminology Criteria for Adverse Events V4.0

#### SECONDARY OUTCOME MEASURES:

- Percent change from baseline in LDL-C at week 80
- Percent change from baseline in non-HDL-C and ApoB at week 80
- Percent change from baseline in total cholesterol/HDL-C ratio and ApoB/ApoA1 at week 80
  - Change in total cholesterol/HDL-C ratio and ApoB/ApoA1 ratio from baseline at week 80
- Change from baseline in LDL-C at week 80
- Change from baseline in steroid hormones (FSH, LH, ACTH, DHEA-S, cortisol, estradiol/testosterone [females/males, respectively]) at week 80
- Change from baseline in Carotid intima-media thickness (cIMT) at week 80
- Subject incidence of abnormal muscle enzyme and liver enzyme levels at week 80
- Change from baseline in height, weight, and pubertal development at week 24, 48 and 80
- Number of participants with abnormal neurological examination findings\* at week 80
- Change from baseline score in the components of the Cogstate battery (cognitive function assessments)† at week 24, 48, and 80

#### KEY INCLUSION CRITERIA:

- Subjects with HeFH:**
- Completed Study 20120123 while still on assigned investigational product and did not experience a treatment-related serious adverse event
- Subjects with HoFH:**
- Male or female, ≥ 10 to ≤ 17 years of age at time of enrollment
  - Diagnosis of HoFH
  - On a low-fat diet and receiving background lipid-lowering therapy
  - Lipid-lowering therapy unchanged for ≥ 4 weeks prior to LDL-C screening; fibrates must be stable for at least 6 weeks prior to screening
  - Fasting LDL-C at screening ≥ 130 mg/dL (3.4 mmol/L)
  - Fasting triglycerides ≤ 400 mg/dL (4.5 mmol/L)

#### KEY EXCLUSION CRITERIA:

- All Subjects:**
- Currently receiving treatment in another investigational device or drug study, or less than 30 days since ending treatment on another investigational device or drug study(ies); except Study 20120123
- Subjects with HoFH:**
- Moderate to severe renal dysfunction
  - Active liver disease or hepatic dysfunction
  - CK > 3 times the ULN at screening

#### ADDITIONAL INFORMATION:

[www.amgentrials.com](http://www.amgentrials.com) (Protocol Number: 20120124)

[www.clinicaltrials.gov](http://www.clinicaltrials.gov) (Identifier: 02624869)

\*The neurologic examination will include assessments of motor, sensory, reflexes, coordination and gait. †The Cogstate battery will include the following tests: Groton Maze Learning Task (GMLT; Executive Function); One Card Learning Test (OCL; Visual Memory); Identification Test (IDN: Attention/Vigilance); Detection Test (DET; Psychomotor Speed) LDL-C = low-density lipoprotein cholesterol; non-HDL-C = non high density lipoprotein cholesterol; ApoB = apolipoprotein B; cIMT = carotid intima-media thickness; QM = once monthly; SC = subcutaneous





REGISTRY

Ongoing Trials

# Atherosclerotic Cardiovascular Disease (ASCVD)

Dyslipidemia



## Registry



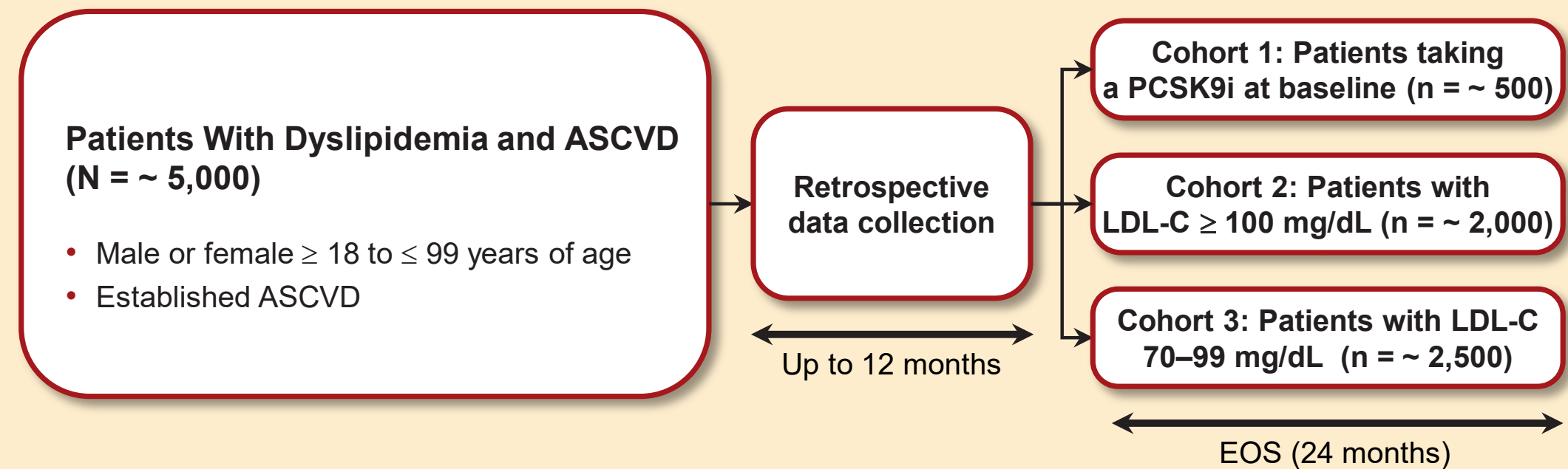
# Getting to an Improved Understanding of Low-Density Lipoprotein Cholesterol and Dyslipidemia Management (GOULD): A Registry of High Cardiovascular Risk Subjects in the United States

Amgen Clinical Study: 20150230

NCT Clinical Study: 02993120

### Getting to an Improved Understanding of Low-Density Lipoprotein Cholesterol and Dyslipidemia Management (GOULD): A Registry of High Cardiovascular Risk Subjects in the United States

#### STUDY DESIGN:



#### PRIMARY ENDPOINT:

- LDL treatment patterns through study completion (an average of 3 years)

#### SECONDARY ENDPOINTS:

- LDL-C levels and measurement patterns through study completion
- Subject characteristics through study completion
- Subject understanding of CV risk through study completion
- Goals of lipid management through study completion
- Attitudes toward LLT through study completion

#### KEY INCLUSION CRITERIA:

- Male or female ≥ 18 to ≤ 99 years of age: ≥ 1 planned visit in the next 12 months
- Established ASCVD defined as meeting ≥ 1 of the following criteria:
  - CAD, prior history of MI, coronary or other arterial revascularization, ischemic stroke or TIA, documented PAD secondary to atherosclerosis, carotid artery stenosis; LDL-C > 69 mg/dL (except in subjects assigned to the PCSK9i cohort)
- For the cohort of ~ 500 subjects taking a PCSK9i at baseline: evidence of a current prescription for an approved PCSK9i and subject confirmation that they have taken a PCSK9i within 30 days prior to enrollment
- For the cohort of ~ 2,000 subjects with LDL-C ≥ 100 mg/dL: confirmation of LDL-C ≥ 100 mg/dL with no change in LLT for 4 weeks
- For the cohort of ~ 2,500 subjects with LDL-C 70-99 mg/dL: confirmation of LDL-C 70-99 mg/dL with no change in LLT for 4 weeks

#### KEY EXCLUSION CRITERIA:

- Unable or unwilling to provide informed consent including but not limited to cognitive or language barriers
- Current or planned participation in an interventional clinical study involving any investigational medical device or drug treatment at the time of enrollment or in the 6 months prior to enrollment
- Life expectancy < 12 months
- Currently pregnant, breastfeeding, or planning to become pregnant\*

\*While pregnant subjects are not eligible for the study, if a site investigator has a subject who becomes pregnant while receiving evolocumab, the investigator will be advised to Amgen's evolocumab pregnancy registry.

#### PURPOSE:

To better understand cholesterol treatment patterns in the context of a changing landscape in subjects with ASCVD.

#### ADDITIONAL INFORMATION:

[www.amgenclinicaltrials.com](http://www.amgenclinicaltrials.com) (Protocol Number: 20150230)

[www.clinicaltrials.gov](http://www.clinicaltrials.gov) (Identifier: NCT02993120)

ASCVD = atherosclerotic cardiovascular disease; CAD = coronary artery disease; CV = cardiovascular; EOS = end of study; LDL-C = low-density lipoprotein cholesterol; LLT = lipid-lowering treatment; MI = myocardial infarction; PAD = peripheral arterial disease; PCSK9i = proprotein convertase subtilisin/kexin type 9 inhibitor; TIA = transient ischemic attack.





REGISTRY

Ongoing Trials

# Atherosclerotic Cardiovascular Disease (ASCVD)

Dyslipidemia



Registry

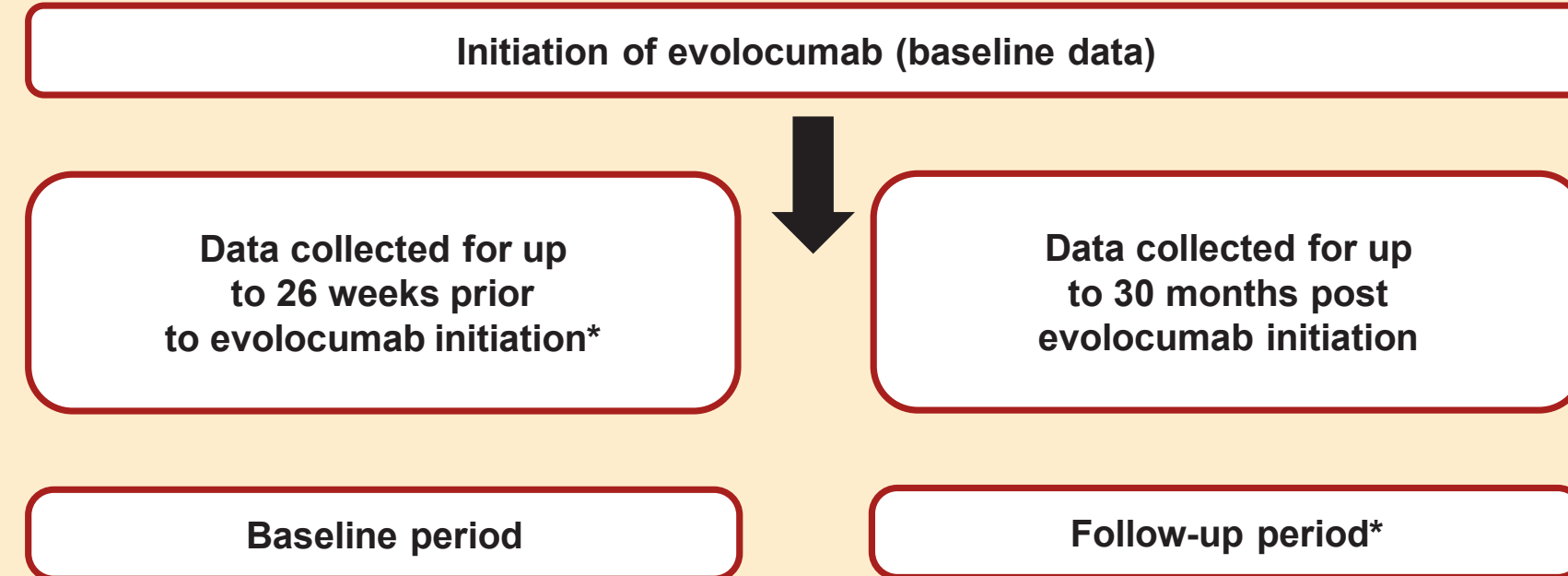
## HEYMANS Chart Review of Evolocumab in Subjects With Hyperlipidaemia

Amgen Clinical Study: 20130296

NCT Clinical Study: 02770131

### Observational Serial Chart Review of Evolocumab Use in European Subjects With Hyperlipidaemia

#### STUDY DESIGN:



\*Where enrollment occurred after evolocumab initiation, follow-up data between initiation and enrollment were captured retrospectively; patients were followed for up to 30 months irrespective of whether they continued to receive evolocumab.

#### STUDY PURPOSE:

To review clinical characteristics of patients who are prescribed evolocumab and how their treatment is managed

#### PRIMARY ENDPOINT:

- Description of clinical characteristics of subjects initiated on evolocumab
  - Age of initiation of evolocumab, gender, familial hypercholesterolaemia status, diabetic status, cardiovascular history, history of statin intolerance

#### SECONDARY ENDPOINTS:

- Describe LDL-C and other cholesterol values over time
  - Detail all cholesterol assessments recorded during the observation period (Total Cholesterol, LDL-C, HDL-C, Non-HDL-C and Triglycerides)
- Describe evolocumab dose over time in mg
- Describe use of other lipid-modifying therapies over time including Type, dose and dose frequency during the observation period
- Describe physician visits
  - Collect all primary and secondary healthcare visit dates and classify as cardiovascular and non-cardiovascular
- Describe hospitalizations from enrollment to end of study
- Describe evolocumab dose frequency over time (Q2W, QM)
- Describe evolocumab administrative device use over time including device details, personal injector, autoinjector or pre-filled syringe throughout the observation period

#### KEY INCLUSION CRITERIA:

- Adults  $\geq 18$  to  $\leq 100$  years of age with informed consent
- Initiated evolocumab at physicians discretion after August 1<sup>st</sup> 2015 (and received at least one dose)

#### KEY EXCLUSION CRITERIA:

- Enrolled in an interventional study of PCSK9 inhibitor within 12 weeks prior to initiation of evolocumab
- Received commercially available PCSK9 inhibitor within 12 weeks prior to initiation of evolocumab

#### ADDITIONAL INFORMATION:

[www.amgentrials.com](http://www.amgentrials.com) (Protocol Number: 20130296)

[www.clinicaltrials.gov](http://www.clinicaltrials.gov) (Identifier: NCT02770131)

LDL-C = low-density lipoprotein cholesterol; HDL-C = high-density lipoprotein cholesterol; PCSK9 = proprotein convertase subtilisin/kexin type 9.





REGISTRY

Ongoing Trials

# Atherosclerotic Cardiovascular Disease (ASCVD)

Dyslipidemia

AMGEN<sup>®</sup>  
Cardiovascular

US and Canada



## DID YOUR PATIENT WITH HIGH CHOLESTEROL, FH\*, OR ASCVD\* BECOME PREGNANT?

MOTHERTOBABY IS ACCEPTING REFERRALS FOR A PREGNANCY REGISTRY STUDY IN WOMEN EXPOSED AND NOT EXPOSED TO EVOLOCUMAB

MotherToBaby depends on healthcare professionals like you to provide referrals to our pregnancy studies. Our studies are observational; participants are not asked to make any changes to their healthcare routine.

Women may qualify for this study if they reside in the U.S. or Canada. We are enrolling women with hypercholesterolemia associated with FH or ASCVD **who have** and those **who have not** used evolocumab in a current or recent pregnancy.

Refer your patients by visiting [MotherToBaby.org](https://www.MotherToBaby.org) or by calling 877.311.8972 to speak directly with a member of our research team. We are available: Monday-Friday 7:30am-6pm PST.

**THIS IS AN INVESTIGATIONAL STUDY OF EVOLOCUMAB SPONSORED BY AMGEN**

\*Familial Hypercholesterolemia (FH), Atherosclerotic Cardiovascular Disease (ASCVD)



**WHO IS MOTHERTOBABY?**  
MotherToBaby Pregnancy Studies are conducted by the non-profit Organization of Teratology Information Specialists (OTIS), the nation's leading authority on the safety of medications and other exposures during pregnancy and lactation, and are coordinated at the University of California, San Diego, CA.  
MotherToBaby is dedicated to providing evidence-based information to mothers, healthcare professionals and the general public about medications and other exposures during pregnancy and while breastfeeding.  
FOR MORE INFORMATION ABOUT MEDICATION USE OR OTHER ENVIRONMENTAL EXPOSURES IN PREGNANCY AND WHILE BREASTFEEDING:  
Visit | [MotherToBaby.org](https://www.MotherToBaby.org)  
Email | [MotherToBaby@ucsd.edu](mailto:MotherToBaby@ucsd.edu)  
Call | 877.311.8972

**Study Cohort Overview**

<b>group I</b> Women diagnosed with hypercholesterolemia associated with FH or ASCVD who were exposed to evolocumab during a current pregnancy.	<b>group II</b> Women diagnosed with hypercholesterolemia associated with FH or ASCVD who were not exposed to a PCSK9 inhibitor during a current pregnancy.
<b>group III</b> Women who have not been diagnosed with hypercholesterolemia associated with FH or ASCVD and who were not exposed to a PCSK9 inhibitor during a current pregnancy.	<b>group IV (case series)</b> Women who were exposed to evolocumab during a current or recent pregnancy but who do not fulfill eligibility criteria for Group I (e.g., retrospective pregnancy report).

USA-165-81158 [www.clinicaltrials.gov/ct2/show/study/NCT03857046](https://www.clinicaltrials.gov/ct2/show/study/NCT03857046)

Press to see the back





REGISTRY

Ongoing Trials

# Atherosclerotic Cardiovascular Disease (ASCVD)

Dyslipidemia

AMGEN®  
Cardiovascular

US and Canada



MotherToBaby

Medications & More During Pregnancy & Breastfeeding  
Ask The Experts

## WHO IS MOTHERTOBABY?

MotherToBaby Pregnancy Studies are conducted by the non-profit Organization of Teratology Information Specialists (OTIS), the nation's leading authority on the safety of medications and other exposures during pregnancy and lactation, and are coordinated at the University of California, San Diego, CA.

MotherToBaby is dedicated to providing evidence-based information to mothers, healthcare professionals and the general public about medications and other exposures during pregnancy and while breastfeeding.

FOR MORE INFORMATION ABOUT MEDICATION USE OR OTHER ENVIRONMENTAL EXPOSURES IN PREGNANCY AND WHILE BREASTFEEDING:

Visit | [MotherToBaby.org](http://MotherToBaby.org)  
Email | [MotherToBaby@ucsd.edu](mailto:MotherToBaby@ucsd.edu)  
Call | 877.311.8972

## Study Cohort Overview

### group I

Women diagnosed with hypercholesterolemia associated with FH or ASCVD who were exposed to evolocumab during a current pregnancy.

### group II

Women diagnosed with hypercholesterolemia associated with FH or ASCVD who were not exposed to a PCSK9 inhibitor during a current pregnancy.

### group III

Women who have not been diagnosed with hypercholesterolemia associated with FH or ASCVD and who were not exposed to a PCSK9 inhibitor during a current pregnancy.

### group IV (case series)

Women who were exposed to evolocumab during a current or recent pregnancy but who do not fulfill eligibility criteria for Group 1 (e.g., retrospective pregnancy report).



Press to see the front





REGISTRY

Ongoing Trials

# Atherosclerotic Cardiovascular Disease (ASCVD)

Dyslipidemia

Europe, South Africa and Australia

**AMGEN**<sup>®</sup>  
Cardiovascular

## YOUR TRUSTED PARTNER IN PREGNANCY HEALTH CARE

Amgen is sponsoring a prospective, observational study of pregnant women that have been exposed to Repatha<sup>®</sup> (evolocumab). The registry is conducted in Europe, South Africa and Australia, and enrolls patients diagnosed with Familial Hypercholesterolemia exposed to Repatha<sup>®</sup> at any point during pregnancy and/or breast-feeding. Participants are not asked to make any changes to their healthcare routine. If a site investigator/health care practitioner has a subject/patient that has, or may have, been exposed to evolocumab while pregnant or breast-feeding, they will be advised to refer the subject to Amgen's evolocumab pregnancy registry.

To learn more about this study you can contact the Amgen Call Center:  
**+ 1 866 572-6436**







# Atherosclerotic Cardiovascular Disease (ASCVD)

AMG 890  
Lp(a) Inhibitor  
PHASE 1<sup>1</sup>

- RNA interference therapy designed to reduce production of apolipoprotein(a), a key component of Lp(a)<sup>2</sup>
- Under investigation for the treatment of dyslipidemia<sup>3</sup>

1. Clinical Trials Website. [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Accessed February 10, 2020.  
2. Amgen And Arrowhead Pharmaceuticals Announce Two Cardiovascular Collaborations. <http://wwwext.amgen.com/media/news-releases/2016/09/amgen-and-arrowhead-pharmaceuticals-announce-two-cardiovascular-collaborations/>. Accessed February 10, 2020.  
3. Bradway RA. Presented at: 36th Annual J.P. Morgan Healthcare Conference; January 9, 2018; Thousand Oaks, CA.

Ongoing Trials

preclinical







AMG 890  
PHASE 1  
Ongoing Trials

# Atherosclerotic Cardiovascular Disease (ASCVD)



## AMG 890 Phase 1 RNA Interference Therapy Study

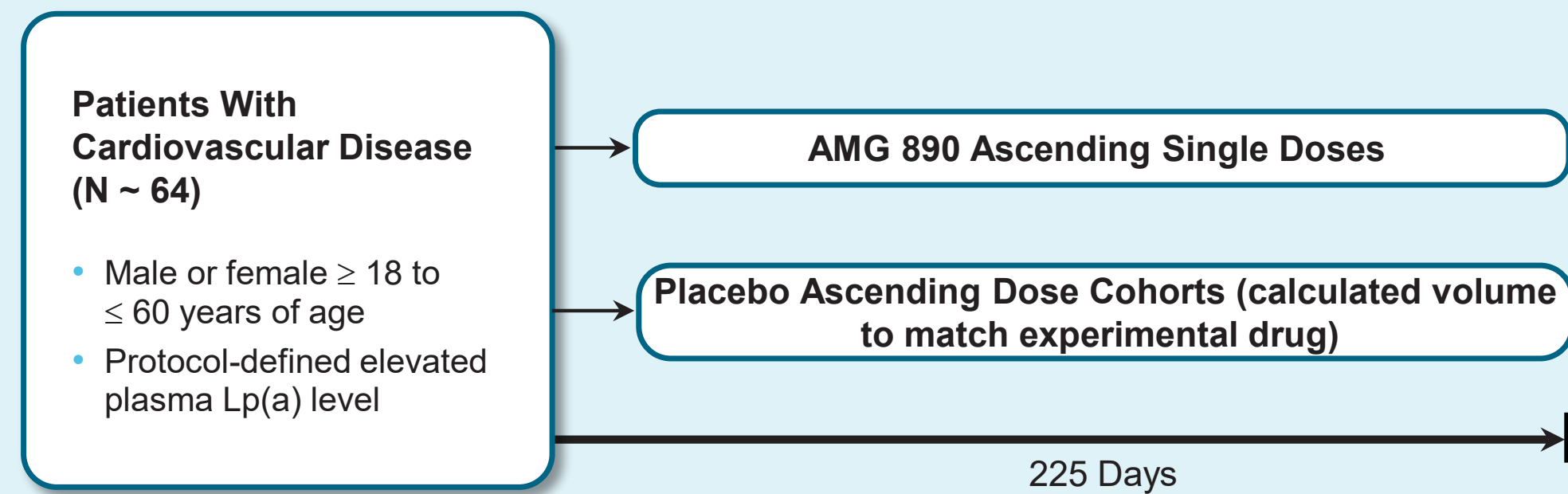
# AMG 890 Safety, Tolerability, Pharmacokinetics and Pharmacodynamics Study of AMG 890 in Subjects With Elevated Plasma Lipoprotein(a)

Amgen Clinical Study: 20170544

NCT Clinical Study: 03626662

**A Phase 1, Randomized, Double-blind, Placebo-controlled, Single Ascending Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of AMG 890 in Subjects With Elevated Plasma Lipoprotein(a)**

**PHASE 1 STUDY DESIGN:**



**CO-PRIMARY OUTCOME MEASURES:**

- Subject incidence of treatment-emergent adverse events (up to 225 days)
- Changes in vital signs, EKG and blood tests (up to 225 days)

**SECONDARY OUTCOME MEASURES:**

- AMG 890 pharmacokinetics ( $C_{max}$ ,  $T_{max}$ , AUC) (up to 225 days)
- Change in plasma Lp(a) over time (up to 225 days)
- Percent change in plasma in Lp(a) over time (up to 225 days)

**KEY INCLUSION CRITERIA:\***

- Male or female ≥ 18 to ≤ 60 years of age
- Protocol-defined elevated plasma Lp(a) level
- BMI ≥ 18 and ≤ 32 kg/m<sup>2</sup> at screening
- Women must be of non-reproductive potential

**KEY EXCLUSION CRITERIA:\***

- Currently receiving treatment in another investigational device or drug study
- Women who are lactating/breastfeeding or who plan to breastfeed while on study or through 90 days after receiving the last dose of investigational product
- History or clinical evidence of bleeding diathesis, any coagulation disorder, or peripheral neuropathy

**STUDY PURPOSE:**

Assess the safety, tolerability, pharmacokinetic and pharmacodynamic effects of AMG 890 in subjects with elevated plasma Lipoprotein(a)

**ADDITIONAL INFORMATION:**

[www.amgentrials.com](http://www.amgentrials.com) (Protocol Number: 20170544)

[www.clinicaltrials.gov](http://www.clinicaltrials.gov) (Identifier: 03626662)

The study is investigational and efficacy and safety have not been determined

\*Note: Not inclusive of all criteria.

AUC = area under the curve; BMI = body mass index;  $C_{max}$  = maximum serum concentration; EKG = electrocardiogram; Lp(a) = lipoprotein(a);  $T_{max}$  = time drug is at maximum serum concentration.