



Amgen Showcases New Data Across Cardiovascular Portfolio At AHA Scientific Sessions 2020: A Virtual Experience

November 9, 2020

New Analyses From the Repatha® (Evolocumab) Cardiovascular Outcomes Study and Real-World GOULD Registry

Primary Results From Phase 3 GALACTIC-HF in Heart Failure Featured in Late-Breaking Clinical Trial Session

First Presentation of Data for Olpasiran, an Investigational siRNA to Reduce Lipoprotein(a) in Patients with Cardiovascular Disease

THOUSAND OAKS, Calif., Nov. 9, 2020 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that data from its cardiovascular (CV) portfolio will be presented at the American Heart Association (AHA) Scientific Sessions 2020: A Virtual Experience, Nov. 13-17, 2020.

Amgen will present new analyses that provide further evidence of the benefits of intensive lipid-lowering to reduce CV events with Repatha® (evolocumab); new data from the GOULD registry, a real-world study with more than 5,000 adults to better understand cholesterol treatment patterns in patients with established cardiovascular disease (CVD); and new first-in-human data for olpasiran (formerly AMG 890), a novel small interfering RNA (siRNA) being developed for patients with CVD with elevated lipoprotein(a) (Lp(a)), a risk factor for CV events. Primary results from GALACTIC-HF, the Phase 3 outcomes trial of omecamtiv mecarbil, an investigational cardiac myosin activator for the treatment of heart failure with reduced ejection fraction (HFrEF), will also be presented in a late-breaking clinical trial session. Amgen announced in October that GALACTIC-HF met its primary composite endpoint and did not meet its secondary endpoint of reduction in CV death.

The new Repatha data contribute to Amgen's PROFICIO (Program to Reduce LDL-C and Cardiovascular Outcomes Following Inhibition of PCSK9 In Different Populations) program of clinical and real-world evidence studies investigating the impact of Repatha on CVD and examining the use of lipid-lowering therapies across multiple patient populations. To date, the PROFICIO program consists of 50 clinical trials including more than 43,000 patients worldwide with eight real-world evidence studies.

"We are committed to serving patients with cardiovascular disease, and these data add further evidence to our PROFICIO program, which supports more intensive and sustained lipid management to achieve guideline recommended LDL-C levels," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "We also look forward to sharing our first data for olpasiran, a novel siRNA, designed to target lipoprotein(a), an independent, heritable risk factor for heart attacks or other cardiovascular events."

Notable data being presented at the meeting include new analyses from the FOURIER trial evaluating Repatha in reducing the risk of major coronary events for atherosclerotic cardiovascular disease (ASCVD) patients on statin therapy, with a history of percutaneous coronary intervention, and a new meta-analysis across 48 randomized clinical trials evaluating the efficacy of lipid-lowering therapies, including Repatha, in reducing low-density lipoprotein cholesterol (LDL-C) levels.

Results from GALACTIC-HF, one of the largest heart failure trials ever conducted will be presented at a live, virtual, embargoed AHA News Briefing on Thursday, Nov. 12, 2020 from 1:30-2:30 p.m. CT. Heart failure affects more than 64 million worldwide,¹ and despite advances in treatment and care over the last decade, hospitalization and mortality rates remain high.

A list of Amgen-sponsored abstracts at AHA Scientific Session 2020: A Virtual Experience can be found below and the full program planner is available [online](#):

GALACTIC-HF Primary Results

- **Omecamtiv Mecarbil in Chronic Heart Failure with Reduced Ejection Fraction: the Global Approach to Lowering Adverse Cardiac Outcomes through Improving Contractility in Heart Failure (GALACTIC-HF) Trial**
Late Breaking Oral Presentation, Friday, Nov. 13, 2020 10:35-10:45 a.m. CT

The following virtual on-demand presentations will be available online from Friday, Nov. 13, 2020 9:00 a.m. to Tuesday, Nov. 17, 2020 8:30 p.m. CT:

Heart Failure Data

- **Characteristics and Outcomes of Patients With Heart Failure With Reduced Ejection Fraction and a Worsening Heart Failure Event** (Abstract P427)
- **Down-Titration of Renin-Angiotensin System Inhibitors After Hospitalization for Heart Failure with Reduced Ejection Fraction** (Abstract P628)
- **Enabling Advanced Real-World Evidence in Heart Failure: A Pilot Study Defining Preferred Approaches to Electronic Health Record Data Use** (Abstract P970)
- **Thirty Day Episode of Care Spending Following Heart Failure Hospitalization Among Medicare Beneficiaries With Heart Failure** (Abstract P975)

Repatha Data

- **A Contemporary Assessment of Lipid Lowering Therapies and Low-Density Lipoprotein Cholesterol in Peripheral**

Artery Disease (Abstract P54)

- **A Novel Genetic Risk Score Predicts Ischemic Stroke in Patients with Cardiometabolic Disease** (Abstract 165)
- **Cardiovascular Outcomes in Patients with Established Atherosclerosis and LDLR Loss of Function: Results from the FOURIER Trial** (Abstract MP352)
- **Effects Of Evolocumab In Patients With Prior Percutaneous Coronary Intervention: An Analysis From The FOURIER Trial** (Abstract P2137)
- **Efficacy of Lowering Low-Density Lipoprotein Cholesterol in Elderly Subjects: A Systematic Review and Meta-Analysis of Randomized Controlled Trials** (Abstract P389)
- **Evolocumab Inhibits the Acute Rise in Lipoprotein(a) in Patients With Non-ST Elevation Myocardial Infarction (NSTEMI)- Results From the EVACS Study** (Abstract P392)
- **Incorporation of High-Sensitivity Troponin along with the AHA/ACC Cholesterol Guidelines for Improved Risk Stratification and Targeted PCSK9 Inhibition in Atherosclerotic Cardiovascular Disease** (Abstract MP512)
- **Reduction with Evolocumab in Complex Coronary Disease Requiring Revascularization: Insights from the FOURIER Trial** (Abstract P394)
- **Relative Efficacy of Alirocumab, Bempedoic Acid, Evolocumab, Ezetimibe and Inclisiran Added to Statins for Reduction of Low-Density Lipoprotein Cholesterol - A Network Meta-Analysis of Randomized Clinical Trials** (Abstract MP460)
- **Relationship Between Baseline Low-Density Lipoprotein Cholesterol and Percent Low-Density Lipoprotein Cholesterol Reduction with Evolocumab in the FOURIER (Further Cardiovascular Outcomes Research with PCSK9 Inhibition in Patients with Elevated Risk) Trial** (Abstract MP461)

Real-World Treatment Patterns

- **Two-year Results of the Getting to an Improved Understanding of Low-density Lipoprotein Cholesterol and Dyslipidemia Management (GOULD) Registry of Patients with Atherosclerotic Cardiovascular Disease (ASCVD)** (Abstract P2255)
- **Underuse of Combination Pharmacotherapy for Management of Dyslipidemia versus Diabetes and Hypertension Among Patients with Atherosclerotic Cardiovascular Disease (ASCVD): Insights from the Getting to an Improved Understanding of Low-density Lipoprotein Cholesterol and Dyslipidemia Management (GOULD) Registry** (Abstract MP459)

Opasiran (AMG 890) Data

- **Safety, Tolerability and Efficacy of Single-Dose AMG 890, a Novel siRNA Targeting Lp(a), in Healthy Subjects and Subjects with Elevated Lp(a)** (Abstract P2338)

About the Repatha CV Outcomes (FOURIER) Study

FOURIER (Further cardiovascular **OU**tcomes Research with PCSK9 Inhibition in Subjects with **E**levated Risk), a multinational Phase 3 randomized, double-blind, placebo-controlled trial, was designed to evaluate whether treatment with Repatha in combination with statin therapy compared to placebo plus statin therapy reduces CV events. The primary endpoint is the time to CV death, myocardial infarction, stroke, hospitalization for unstable angina, or coronary revascularization. The key secondary endpoint is the time to CV death, myocardial infarction or stroke.

Eligible patients with high cholesterol (LDL-C ≥ 70 mg/dL or non-high-density lipoprotein cholesterol [non-HDL-C] ≥ 100 mg/dL) and clinically evident ASCVD at more than 1,300 study locations around the world were randomized to receive Repatha subcutaneous 140 mg every two weeks or 420 mg monthly plus effective statin dose; or placebo subcutaneous every two weeks or monthly plus effective statin dose. Optimized statin therapy was defined as at least atorvastatin 20 mg or equivalent daily with a recommendation for at least atorvastatin 40 mg or equivalent daily where approved. The study was event-driven and continued until at least 1,630 patients experienced a key secondary endpoint.

FOURIER is part of Amgen's PROFICIO (**P**rogram to **R**educe LDL-C and cardiovascular **O**utcomes **F**ollowing Inhibition of PCSK9 In different **p**Opulations) program of clinical studies investigating the impact of Repatha on LDL-C and CVD across multiple populations at high CV risk, including those managed by statins, statin-intolerant patients, those with genetic disorders and patients with atherosclerosis. To date, the PROFICIO program consists of 50 trials including more than 43,000 patients worldwide.

GOULD Study Design

Getting to an Impr**O**ved Understanding of Low-Density Lipoprotein and Dyslipidemia Management (GOULD) Registry is a multicenter, observational registry of ASCVD patients, to describe LDL-C treatment patterns in the U.S. and track them over time. This registry and subsequent analysis sought to better understand the adaptability of lipid management guidelines for patients with ASCVD.

From December 2016 to April 2018, interactive phone surveys with the lead physicians from each of the 120 U.S. centers participating in the registry (1 physician from each center) and patients (N=5,006) were conducted. Patients with ASCVD receiving any pharmacological lipid-lowering therapy were eligible for enrollment in 1 of 3 cohorts: 1) currently receiving a PCSK9i antibody, 2) no PCSK9i and LDL-C 70-99 mg/dL, and 3) no PCSK9i and LDL-C ≥ 100 mg/dL. Patients underwent a 1-year retrospective chart review, followed by chart reviews and interviews every 6 months for 2 years.

GALACTIC-HF: Trial Design

GALACTIC-HF,² (**G**lobal Approach to **L**owering **A**dverse **C**ardiac **O**utcomes **T**hrough **I**mproving **C**ontractility in **H**eart **F**ailure), one of the largest Phase 3 global CV outcomes studies in heart failure ever conducted, enrolled 8,256 patients in 35 countries with HFrEF, New York Heart Association (NYHA) class II-IV, left ventricular ejection fraction (LVEF) $\leq 35\%$, elevated natriuretic peptides and either current hospitalization for heart failure or

history of hospitalization or emergency department visit for heart failure within a year. Patients were randomized to either oral placebo or a starting dose of 25 mg omecamtiv mecarbil twice daily (maintenance dose of 50 mg, 37.5 mg, or 25 mg twice daily) guided by pharmacokinetic-guided dose selection. A blood test, the QMS Omecamtiv Mecarbil Immunoassay (the OM Test) was used to measure plasma levels of omecamtiv mecarbil in each patient in order to guide selection of the appropriate maintenance dose.

The primary composite endpoint of this double-blind, placebo-controlled, event-driven trial was time to CV death or first heart failure event (heart failure hospitalization and other urgent treatment for heart failure). Secondary endpoints were: time to CV death, patient reported outcomes (measured by Kansas City Cardiomyopathy Questionnaire [KCCQ] Total Symptom Score [TSS]), time to first heart failure hospitalization and time to all-cause death.

About Omecamtiv Mecarbil and the Phase 3 Clinical Trials Program

Omecamtiv mecarbil is an investigational selective cardiac myosin activator, the first of a novel class of myotropes³ designed to directly target the contractile mechanisms of the heart, binding to and recruiting more cardiac myosin heads to interact with actin during systole. Preclinical research has shown that omecamtiv mecarbil increases cardiac contractility without increasing intracellular myocyte calcium concentrations or myocardial oxygen consumption.^{4,5,6} Cardiac myosin is the cytoskeletal motor protein in the cardiac muscle cell that is directly responsible for converting chemical energy into the mechanical force resulting in cardiac contraction.

Omecamtiv mecarbil is being developed for the potential treatment of heart failure with reduced ejection fraction (HFrEF) under a collaboration between Amgen and Cytokinetics, with funding and strategic support from Servier.

About Heart Failure

Heart failure is a grievous condition that affects more than 64 million people worldwide¹ about half of whom have reduced left ventricular function.^{7,8} It is the leading cause of hospitalization and readmission in people age 65 and older.^{9,10} Despite broad use of standard treatments and advances in care, the prognosis for patients with heart failure is poor.¹¹ An estimated one in five people over the age of 40 are at risk of developing heart failure, and approximately 50 percent of people diagnosed with heart failure will die within five years of initial hospitalization.^{12,13}

About Olpasiran

Olpasiran (formerly known as AMG 890) is a small interfering RNA (siRNA) that targets lipoprotein(a), also known as Lp(a). It is being investigated for the treatment of ASCVD.

About Amgen in the Cardiovascular Therapeutic Area

Building on more than three decades of experience in developing biotechnology medicines for patients with serious illnesses, Amgen is dedicated to addressing important scientific questions to advance care and improve the lives of patients with cardiovascular disease, the leading cause of morbidity and mortality worldwide.¹⁴ Amgen's research into cardiovascular disease, and potential treatment options, is part of a growing competency at Amgen that utilizes human genetics to identify and validate certain drug targets. Through its own research and development efforts, as well as partnerships, Amgen is building a robust cardiovascular portfolio consisting of several approved and investigational molecules in an effort to address a number of today's important unmet patient needs, such as elevated lipids, including high cholesterol and Lp(a), and heart failure.

About Amgen

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its biologics manufacturing expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be the world's largest independent biotechnology company, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

About Repatha[®] (evolocumab)

Repatha is a human monoclonal antibody that inhibits proprotein convertase subtilisin/kexin type 9 (PCSK9). Repatha binds to PCSK9 and inhibits circulating PCSK9 from binding to the low-density lipoprotein (LDL) receptor (LDLR), preventing PCSK9-mediated LDLR degradation and permitting LDLR to recycle back to the liver cell surface. By inhibiting the binding of PCSK9 to LDLR, Repatha increases the number of LDLRs available to clear LDL from the blood, thereby lowering LDL-C levels.¹⁵

Repatha is approved in more than 75 countries, including the U.S., Japan, Canada, Australia, China and in all 28 countries that are members of the European Union. Applications in other countries are pending.

Important U.S. Product Information

Repatha is a PCSK9 (proprotein convertase subtilisin/kexin type 9) inhibitor antibody indicated:

- to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease.
- as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia [HeFH]) to reduce low-density lipoprotein cholesterol (LDL-C).
- as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.

The safety and effectiveness of Repatha have not been established in pediatric patients with HoFH who are younger than 13 years old or in pediatric patients with primary hyperlipidemia or HeFH.

Important U.S. Safety Information

Contraindication: Repatha is contraindicated in patients with a history of a serious hypersensitivity reaction to Repatha. Serious hypersensitivity reactions including angioedema have occurred in patients treated with Repatha.

Allergic reactions: Hypersensitivity reactions (e.g. angioedema, rash, urticaria) have been reported in patients treated with Repatha, including some that led to discontinuation of therapy. If signs or symptoms of serious allergic reactions occur, discontinue treatment with Repatha, treat according to the standard of care, and monitor until signs and symptoms resolve.

Adverse reactions: The most common adverse reactions (>5% of patients treated with Repatha and occurring more frequently than placebo) were: nasopharyngitis, upper respiratory tract infection, influenza, back pain, and injection site reactions.

From a pool of the 52-week trial and seven 12-week trials: Local injection site reactions occurred in 3.2% and 3.0% of Repatha-treated and placebo-treated patients, respectively. The most common injection site reactions were erythema, pain, and bruising.

Allergic reactions occurred in 5.1% and 4.7% of Repatha-treated and placebo-treated patients, respectively. The most common allergic reactions were rash (1.0% versus 0.5% for Repatha and placebo, respectively), eczema (0.4% versus 0.2%), erythema (0.4% versus 0.2%), and urticaria (0.4% versus 0.1%).

The most common adverse reactions in the Cardiovascular Outcomes Trial (>5% of patients treated with Repatha and occurring more frequently than placebo) were: diabetes mellitus (8.8% Repatha, 8.2% placebo), nasopharyngitis (7.8% Repatha, 7.4% placebo), and upper respiratory tract infection (5.1% Repatha, 4.8% placebo).

Among the 16,676 patients without diabetes mellitus at baseline, the incidence of new-onset diabetes mellitus during the trial was 8.1% in patients assigned to Repatha compared with 7.7% in those assigned to placebo.

Homozygous Familial Hypercholesterolemia (HoFH): The adverse reactions that occurred in at least two patients treated with Repatha and more frequently than placebo were: upper respiratory tract infection, influenza, gastroenteritis, and nasopharyngitis.

Immunogenicity: Repatha is a human monoclonal antibody. As with all therapeutic proteins, there is a potential for immunogenicity with Repatha.

Please contact Amgen Medinfo at 800-77-AMGEN (800-772-6436) or 844-REPATHA (844-737-2842) regarding Repatha® availability or find more information, including full [Prescribing Information](#), at www.amgen.com and www.Repatha.com.

Amgen Forward-Looking Statements

This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including any statements on the outcome, benefits and synergies of collaborations, or potential collaborations, with any other company, including BeiGene, Ltd. or any collaboration or potential collaboration in pursuit of therapeutic antibodies against COVID-19 (including statements regarding such collaboration's, or our own, ability to discover and develop fully-human neutralizing antibodies targeting SARS-CoV-2 or antibodies against targets other than the SARS-CoV-2 receptor binding domain, and/or to produce any such antibodies to potentially prevent or treat COVID-19), or the Otezla® (apremilast) acquisition, including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion, as well as estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes, effects of pandemics or other widespread health problems such as the ongoing COVID-19 pandemic on our business, outcomes, progress, or effects relating to studies of Otezla as a potential treatment for COVID-19, and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including its most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and current reports on Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those Amgen projects. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints Amgen has selected. Amgen develops product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify safety, side effects or manufacturing problems with its products, including its devices, after they are on the market.

Amgen's results may be affected by its ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing its products and global economic conditions. In addition, sales of Amgen's products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, Amgen's research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Amgen's business may be impacted by government investigations, litigation and product liability claims. In addition, Amgen's business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If Amgen fails to meet the compliance obligations in the corporate integrity agreement between Amgen and the U.S. government, Amgen could become subject to significant sanctions. Further, while Amgen routinely obtains patents for its products and technology, the protection offered by its patents and patent applications may be challenged, invalidated or circumvented by its competitors, or Amgen may fail to prevail in present and future intellectual property litigation. Amgen performs a substantial amount of its commercial manufacturing activities at a few key facilities, including in

Puerto Rico, and also depends on third parties for a portion of its manufacturing activities, and limits on supply may constrain sales of certain of its current products and product candidate development. An outbreak of disease or similar public health threat, such as COVID-19, and the public and governmental effort to mitigate against the spread of such disease, could have a significant adverse effect on the supply of materials for Amgen's manufacturing activities, the distribution of Amgen's products, the commercialization of Amgen's product candidates, and Amgen's clinical trial operations, and any such events may have a material adverse effect on Amgen's product development, product sales, business and results of operations. Amgen relies on collaborations with third parties for the development of some of its product candidates and for the commercialization and sales of some of its commercial products. In addition, Amgen competes with other companies with respect to many of its marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for Amgen's products are supplied by sole third-party suppliers. Certain of Amgen's distributors, customers and payers have substantial purchasing leverage in their dealings with Amgen. The discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on its business and results of operations. Amgen's efforts to collaborate with or acquire other companies, products or technology, and to integrate the operations of companies or to support the products or technology Amgen has acquired, may not be successful. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of Amgen's systems and Amgen's data. Amgen's stock price may be volatile and may be affected by a number of events. Amgen's business performance could affect or limit the ability of the Amgen Board of Directors to declare a dividend or its ability to pay a dividend or repurchase its common stock. Amgen may not be able to access the capital and credit markets on terms that are favorable to it, or at all.

The scientific information discussed in this news release related to Amgen's product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates.

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- ¹⁵ Repatha Prescribing Information; Amgen, Thousand Oaks, CA, 2018.



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