AMGEN TO PRESENT NEW REPATHA® (EVOLOCUMAB) AND OLPASIRAN DATA AT ACC

March 1, 2023

Combined Data From FOURIER and FOURIER-OLE Studies Show Earlier, Longer Use of Repatha Reduces Total CV Events

Analysis From Phase 2 OCEAN(a)-DOSE Study Shows Olpasiran Markedly Reduced Lp(a) Concentration Irrespective of Baseline Level

Amgen Convenes First LDL-C Action Summit to Help Improve State of Cardiovascular Disease Care in the U.S.

THOUSAND OAKS, Calif., March 1, 2023 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced new Repatha® (evolocumab) combined data from the Phase 3 FOURIER and FOURIER Open Label Extension (OLE) studies and the Phase 2 OCEAN(a)-DOSE study of investigational olpasiran, an siRNA that reduces lipoprotein(a) [Lp(a)] by more than 90%. Additional data from Amgen's Center for Observational Research and Amgen funded investigator studies, including YELLOW-III from Mount Sinai will be presented at the American College of Cardiology's 72nd Annual Scientific Session together with World Heart Federation's World Congress of Cardiology (ACC.23/WCC) in New Orleans, LA, March 4-6, 2023.

The Repatha data evaluated all primary endpoint events from the patients enrolled in the parent FOURIER study (n=27,564), with a median follow up of 2.2 years, and for patients who received Repatha during FOURIER-OLE (n=6,635), for an additional 3 years of follow up. These findings showed that over the duration of follow-up, patients with atherosclerotic cardiovascular disease (ASCVD) who were already receiving statin therapy had a reduction in adverse cardiovasclar outcomes with earlier initiation of Repatha. This was shown by the reduction in total cardiovascular (CV) endpoint events (cardiovascular disease, myocardial infarction, stroke, unstable angina or coronary revascularization) in patients that had initiated Repatha in the parent study and continued Repatha in the OLE, as compared to those who were in the standard of care group in the parent study and only initiated Repatha during the OLE.

"Amgen is at the forefront of lipid research and we are focused on addressing some of the most significant cardiovascular disease risk factors, including unmanaged LDL-C and Lp(a)," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "The robust body of evidence on Repatha continues to underscore its clinical importance as a transformative therapy in lowering LDL-C to reduce CV events like heart attack and stroke in patients with ASCVD. We are proud to provide Repatha to millions of patients worldwide at an affordable cost."

Olpasiran is an investigational siRNA-based therapy that has been shown to reduce Lp(a) by more than 90% in Phase 2. A new analysis of the OCEAN(a) Dose study will examine whether the percentage of Lp(a) reduction with olpasiran is affected by baseline Lp(a) concentrations. The results showed that olpasiran markedly reduced Lp(a) concentration irrespective of baseline level in those with ASCVD and Lp(a) >150 nmol/L. These findings provide important insights into how much Lp(a) reduction may be achieved with olpasiran in settings where the Lp(a) burden is very high.

While in New Orleans, Amgen will also convene the first ever LDL-C Action Summit to address the state of cardiovascular disease (CVD) care in the United States. This first meeting will bring together key CVD community stakeholders, including the American College of Cardiology, American Heart Association, Cardio Health Alliance, Baim Institute for Clinical Research and PERFUSE, Family Heart Foundation, National Forum and the National Lipid Association, to understand the challenges in the treatment landscape and discuss strategies and opportunities for collaboratively improving lipid management among the highest risk ASCVD patients.

"I look forward to presenting at this important summit convening multiple stakeholders across academia, societies, and industry to address the gaps in ASCVD care," said C. Michael Gibson, M.D., CEO of the non-profit Baim Institute of Clinical Research, and Professor of Medicine, Harvard. "Despite the clear benefits of LDL lowering, people at risk are not being identified, and when they are, they reach the guidelines goal only a third of the time. The implementation science needs to be stepped up to match the amazing basic/clinical science of lipid lowering. We need to work together to get this changed."

For more information on the Amgen abstracts, see below. To learn more about what Amgen is doing to address CVD, please visit Amgen.com and follow us on Twitter, LinkedIn, Instagram, TikTok and YouTube.

Amgen Abstracts

- **Low-Density Lipoprotein Cholesterol Testing Following Myocardial Infarction Hospitalization Among Medicare Beneficiaries**
  Digital Presentation (#1135-005), Saturday, March 4

- **Characteristics of Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitor Monoclonal Antibody New Users and Changes in LDL-C Using Real-World Data: A U.S. Perspective**
  Moderated Poster Session (#1008-05), Saturday, March 4, 10:00-10:10am CST

- **Reduction in Total Cardiovascular Events with the PCSK9 Inhibitor Evolocumab in Patients with Cardiovascular Disease in the Combined FOURIER and FOURIER Open-Label Extension (OLE) Studies**
  Moderated Poster (#1003-13), Theater, Saturday, March 4, 11:00-11:10am CST

- **Use of Negative Control Outcomes to Assess the Comparability of PCSK9i mAb Treatment Protocols Following Myocardial Infarction**
  Flatboard Poster (#1347-138), Saturday, March 4, 1:45-2:30pm CST

- **Association of Baseline Lipoprotein(a) and Percentage of Lipoprotein(a) Lowering with Olpasiran**
  Moderated Poster (#1027-05), Saturday, March 4, 3:15-3:25pm CST

Investigator Sponsored Studies (ISS)

- **Effect of Evolocumab on Coronary Plaque Characteristics in Stable Coronary Artery Disease: A Multimodality Imaging Study (YELLOW-III)**
  Late-Breaker (#403-14), Saturday Mar 4, 12:45 pm - 12:55 pm

- **Pragmatic Implementation Science to Assess Lipid Optimization in Peripheral Artery Disease: Primary Results of the OPTIMIZE PAD-1 Trial**
  Flatboard Poster (#1726-007) Monday Mar 6, 2023,10:45 am - 11:30 am

- **Inhibition of PCSK9 with evolocumab modulates immune-cell activation in high-risk ASCVD patients – The Metchnikoff Clinical Trial**
  Moderated Poster (#1008-07), Saturday Mar 4, 2023, 10:15 am - 10:25 am

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. Repatha has been studied for 12 years in 50 clinical trials with over 51,000 patients.

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

About Olpasiran
Olpasiran (formerly known as AMG 890) is a small interfering RNA (siRNA) that targets lipoprotein(a), also known as Lp(a). We look forward to studying this treatment further in Phase 3 clinical trial, which is currently recruiting.

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 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 one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

Amgen is one of the 30 companies that comprise the Dow Jones Industrial Average and is also part of the Nasdaq-100 index. In 2022, Amgen was named one of the "World's Best Employers" by Forbes and one of "America's 100 Most Sustainable Companies" by Barron's.

Repatha (evolocumab) Important U.S. Product Information

INDICATIONS
Repatha® is indicated:

- In adults with established cardiovascular disease to reduce the risk of myocardial infarction, stroke, and coronary revascularization
- As an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)–lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL–C
- As an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C
- As an adjunct to other LDL–C-lowering therapies in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH), to reduce LDL–C

The safety and effectiveness of Repatha® have not been established in pediatric patients with HeFH or HoFH who are younger than 10 years old or in pediatric patients with other types of hyperlipidemia.

IMPORTANT SAFETY INFORMATION

- **Contraindication:** Repatha® is contraindicated in patients with a history of a serious hypersensitivity reaction to evolocumab or any of the excipients in Repatha®. Serious hypersensitivity reactions including angioedema have occurred in patients treated with Repatha®.

- **Hypersensitivity Reactions:** Hypersensitivity reactions, including angioedema, have been reported in patients treated with Repatha®. If signs or symptoms of serious hypersensitivity reactions occur, discontinue treatment with Repatha®, treat according to the standard of care, and monitor until signs and symptoms resolve.

- **Adverse Reactions in Adults with Primary Hyperlipidemia:** The most common adverse reactions (>5% of patients treated with Repatha® and 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. Hypersensitivity reactions occurred in 5.1% and 4.7% of Repatha®-treated and placebo-treated patients, respectively. The most common hypersensitivity 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%).

- **Adverse Reactions in the Cardiovascular Outcomes Trial:** The most common adverse reactions (>5% of patients treated with Repatha® and 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 treated with Repatha® compared with 7.7% in patients that received placebo.

- **Adverse Reactions in Pediatric Patients with HeFH:** The most common adverse reactions (>5% of patients treated with Repatha® and more frequently than placebo) were: nasopharyngitis, headache, oropharyngeal pain, influenza, and upper respiratory tract infection.

- **Adverse Reactions in Adults and Pediatric Patients with HoFH:** In a 12-week study in 49 patients, 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. In an open-label extension study in 106 patients, including 14 pediatric patients, no new adverse reactions were observed.

- **Immunogenicity:** Repatha® is a human monoclonal antibody. As with all therapeutic proteins, there is 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., Kyowa-Kirin Co., Ltd., or any collaboration to manufacture therapeutic antibodies against COVID-19), the performance of Otezla® (apremilast) (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), the Five Prime Therapeutics, Inc. acquisition, the Teneobio, Inc. acquisition, the ChemoCentryx, Inc. acquisition, or the proposed acquisition of Horizon Therapeutics plc, 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, 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 our 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 we project. 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 us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints we have selected. We develop 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 we may have believed at the time of entering into such relationship. Also, we or others could identify safety, side effects or manufacturing problems with our products, including our devices, after they are on the market.

Our results may be affected by our 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 our products and global economic conditions. In addition, sales of our 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, our research, testing, pricing, marketing and other operations are subject to

extensive regulation by domestic and foreign government regulatory authorities. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our 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 our manufacturing activities, the distribution of our products, the commercialization of our product candidates, and our clinical trial operations, and any such events may have a material adverse effect on our product development, product sales, business and results of operations. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. The discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations. Our 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 we have acquired, may not be successful. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our systems and our data. Our stock price is volatile and may be affected by a number of events. Our business and operations may be negatively affected by the failure, or perceived failure, of achieving our environmental, social and governance objectives. The effects of global climate change and related natural disasters could negatively affect our business and operations. Global economic conditions may magnify certain risks that affect our business. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

The scientific information discussed in this news release related to our 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. Further, any scientific information discussed in this news release relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration for the products. The products are not approved for the investigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses.

CONTACT: Amgen, Thousand Oaks
Megan Fox, 805-447-1423 (media)
Jessica Akopyan, 805-440-5721 (media)
Arvind Sood, 805-447-1060 (investors)

View original content to download multimedia:https://www.prnewswire.com/news-releases/amgen-to-present-new-repatha-evolocumab-and-olpasiran-data-at-acc-301759141.html

SOURCE Amgen