Amgen To Present New Long-Term Repatha™ (Evolocumab) Data Analysis At ESC Congress 2015

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Featured Data Evaluates One-Year Safety and Efficacy of Repatha in Patients Who Cannot Tolerate Statins

THOUSAND OAKS, Calif., Aug. 25, 2015 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that it will present six abstracts at the upcoming ESC Congress 2015, organized by the European Society of Cardiology, being held Aug. 29 – Sept. 2 in London. Data will be presented evaluating Repatha™ (evolocumab), a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor approved in the European Union (EU) for the treatment of patients with uncontrolled cholesterol who require additional intensive low-density lipoprotein cholesterol (LDL-C) reduction.[1]

"This has been a historic year for Amgen's cardiovascular franchise with multiple regulatory milestones, including the recent EU approval of Repatha, the first PCSK9 inhibitor approved by a regulatory agency in the world, and we're excited to continue the momentum with new data being presented at this year's ESC Congress," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "We are committed to continuing to evaluate Repatha and look forward to sharing long-term safety and efficacy data in patients who are unable to tolerate effective doses of statins, as well as findings on consistent LDL-C reductions in different patient subgroups."

In addition to clinical results, data from Amgen's Center for Observational Research will also be presented, including a Rapid Fire Abstract presentation on statin usage and outcomes among Medicare beneficiaries, a presentation on the identification and characterization of patients with heterozygous familial hypercholesterolemia (HeFH), and a discussion examining the burden of cardiovascular hospitalizations in patients who have had a myocardial infarction. In addition, Global Health Economic (GHE) data on the identification and management of patients who cannot tolerate statins will be presented.

Amgen-sponsored abstracts and satellite symposium at ESC Congress 2015 include:

Repatha

- **Clinical equivalence of evolocumab among patient subgroups in PROFICIO: a pooled analysis of 3146 patients from phase 3 studies**
  Abstract P1756, Poster Presentation, Sunday, Aug. 30, 8:30 a.m.-12:30 p.m. BST (Poster Area)
- **Long-term safety and efficacy of evolocumab in patients with statin intolerance**
  Abstract P5968, Moderated Poster Presentation, Tuesday, Sept. 1, 3:47-3:55 p.m. BST (Moderated Poster Station – Poster Area)
- **Satellite Symposium – PCSK9 inhibition: an important step forward in treating dyslipidemia in high-risk patients**
  Tuesday, Sept. 1, 12:45-1:45 p.m. BST (Ankara – Village 7)

Observational Research

- **Burden of cardiovascular hospitalizations following myocardial infarction among older adults**
  Abstract P3667, Poster Presentation, Monday, Aug. 31, 8:30 a.m.-12:30 p.m. BST (Poster Area)
- **Identification and characterization of heterozygous familial hypercholesterolemia patients using the Vanderbilt University Medical Center Synthetic Derivative database**
  Abstract P5374, Poster Presentation, Tuesday, Sept. 1, 8:30 a.m.-12:30 p.m. BST (Poster Area)
- **Patterns of statin use and outcomes following myocardial infarction among Medicare beneficiaries**
  Abstract P6653, Rapid Fire Abstract Presentation, Wednesday, Sept. 2, 9:33-9:42 a.m. BST (Victoria Park – The Hub)

Health Economics

- **Identification and management of statin-intolerance: a survey of clinicians from 13 countries**
  Abstract P1677, Poster Presentation, Sunday, Aug. 30, 8:30 a.m.-12:30 p.m. BST (Poster Area)

About Repatha™ (evolocumab)

Repatha™ (evolocumab) is a human monoclonal antibody that inhibits proprotein convertase subtilisin/kexin type 9 (PCSK9).[1] PCSK9 is a protein that targets LDL receptors for degradation and thereby reduces the liver's ability to remove LDL-C, or "bad" cholesterol, from the blood.[2] Repatha, developed by Amgen scientists, is designed to bind to PCSK9 and inhibit PCSK9 from binding to LDL receptors on the liver surface. In the absence of PCSK9, there are more LDL receptors on the surface of the liver to remove LDL-C from the blood.[1]

In the EU, the European Commission (EC) approved Repatha for:

- The treatment of adults with primary hypercholesterolemia (heterozygous familial [HeFH] and non-familial) or mixed dyslipidemia, as an adjunct to diet:
  - in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or
  - alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

- The treatment of adults and adolescents aged 12 years and over with homozygous FH in combination with other lipid-lowering therapies.

The effect of Repatha on cardiovascular morbidity and mortality has not yet been determined.

Important EU Safety Information

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Dosage and Administration: Repatha is for subcutaneous injection into the abdomen, thigh or upper arm region. Prior to initiating Repatha, secondary causes of hyperlipidaemia or mixed dyslipidaemia (e.g., nephrotic syndrome, hypothyroidism) should be excluded. Primary hypercholesterolaemia and mixed dyslipidaemia in adults: The recommended dose of Repatha is either 140 mg every two weeks or 420 mg once monthly; both doses are clinically equivalent. The safety and efficacy of Repatha in children aged less than 18 years has not been established. Homozygous familial hypercholesterolaemia in adults and adolescents aged 12 years and over: The initial recommended dose is 420 mg once monthly. After 12 weeks of treatment, dose frequency can be up titrated to 420 mg once every 2 weeks if a clinically meaningful response is not achieved. Patients on apheresis may initiate treatment with 420 mg every two weeks to correspond with their apheresis schedule. The safety and efficacy of Repatha in children aged less than 12 years has not been established.

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Special Warnings and Precautions: Renal impairment: Patients with severe renal impairment (defined as eGFR < 30 mL/min/1.73 m^2) have not been studied. Repatha should be used with caution in patients with severe renal impairment. Hepatic impairment: In patients with moderate hepatic impairment, a reduction in total evolocumab exposure was observed that may lead to a reduced effect on LDL-C reduction. Therefore, close monitoring may be warranted in these patients. Patients with severe hepatic impairment (Child-Pugh C) have not been studied. Repatha should be used with caution in patients with severe hepatic impairment. Dry natural rubber: The needle cover of the glass pre-filled syringe and of the pre-filled pen is made from dry natural rubber (a derivative of latex), which may cause allergic reactions. Sodium content: Repatha contains less than 1 mmol sodium (23 mg) per dose, i.e. it is essentially 'sodium-free'.

Interactions: No formal drug-drug interaction studies have been conducted for Repatha. No studies on pharmacokinetic and pharmacodynamics interaction between Repatha and lipid-lowering drugs other than statins and ezetimibe have been conducted.

Fertility, Pregnancy and Lactation: There are no or limited amount of data from the use of Repatha in pregnant women. Repatha should not be used during pregnancy unless the clinical condition of the woman requires treatment with evolocumab. It is unknown whether evolocumab is excreted in human milk. A risk to breastfed newborns/infants cannot be excluded. No data on the effect of evolocumab on human fertility are available.

Undesirable Effects: The following common (≥ 1/100 to < 1/10) adverse reactions have been reported in pivotal, controlled clinical studies: influenza, nasopharyngitis, upper respiratory tract infection, rash, nausea, back pain, arthralgia, injection site reactions. Please consult the SmPC for a full description of undesirable effects.

Pharmaceutical Precautions: Store in a refrigerator (2 degrees C – 8 degrees C). Do not freeze. Keep the pre-filled syringe or the pre-filled pen in the original carton in order to protect from light. If removed from the refrigerator, Repatha may be stored at room temperature (up to 25 degrees C) in the original carton and must be used within 1 week.

About Amgen Cardiovascular
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.[3] 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 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 high cholesterol 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 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.

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

Forward-Looking Statements
This news release contains forward-looking statements that are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including 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 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 (SEC) reports filed by Amgen, including Amgen's most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen's most recent Forms 10-K, 10-Q and 8-K for additional information on the uncertainties and risk factors related to our business. Unless otherwise noted, Amgen is providing this information as of Aug. 25, 2015, and expressly disclaims any duty to update information contained in this

news release.

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. 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 after they are on the market. Our business may be impacted by government investigations, litigation and products liability claims. We depend on third parties for a significant portion of our manufacturing capacity for the supply of certain of our current and future products and limits on supply may constrain sales of certain of our current products and product candidate development.

In addition, sales of our products are affected by the reimbursement policies imposed by third-party payors, 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 as well as U.S. legislation affecting pharmaceutical pricing and reimbursement. Government and others' regulations and reimbursement policies may affect the development, usage and pricing of our products. In addition, we compete with other companies with respect to some of our marketed products as well as for the discovery and development of new products. We believe that some of our newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Our products may compete against products that have lower prices, established reimbursement, superior performance, are easier to administer, or that are otherwise competitive with our products. In addition, 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 and there can be no guarantee of our ability to obtain or maintain patent protection for our products or product candidates. We cannot guarantee that we will be able to produce commercially successful products or maintain the commercial success of our existing products. Our stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of our products or product candidates. Further, 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 integrate the operations of companies we have acquired may not be successful. We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our ongoing restructuring plan. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or their ability to pay a dividend or repurchase our common stock.

The scientific information discussed in this news release related to our product candidates is specific to the European Union. Such product candidates are not approved by the U.S. Food and Drug Administration (FDA), and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates in the U.S.

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