Amgen Canada Inc.
6775 Financial Dr
Mississauga, ON L5N 0A4
Telephone 905-285-3000
www.Amgen.ca

News Release

Please note: This information is for Canadian media only

HEALTH CANADA APPROVES AMGEN'S NEW CHOLESTEROL-LOWERING MEDICATION REPATHA™ (EVOLOCUMAB)

Repatha Reduced LDL-C by up to 75 Per Cent Compared With Placebo

First in a New Class of Cholesterol-Lowering Drugs Offers Canadian Physicians and Patients a New Choice in Cholesterol Management

MISSISSAUGA, ON (September 15, 2015) – Amgen Canada Inc. today announced that Health Canada has approved a new cholesterol-lowering medication, Repatha™ (evolocumab). Repatha is a fully human monoclonal antibody that inhibits proprotein convertase subtilisin/kexin type 9 (PCSK9), a protein that reduces the liver's ability to remove low-density lipoprotein cholesterol (LDL-C), or "bad" cholesterol, from the blood.[1] Repatha is indicated as an adjunct to diet and maximally tolerated statin therapy in adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (CVD), who require additional lowering of LDL-C; and as an adjunct to diet and other LDL-lowering therapies in adults and adolescent patients aged 12 and over with homozygous familial hypercholesterolemia (HoFH), who require additional lowering of LDL-C. The effect of Repatha on cardiovascular morbidity and mortality has not been determined.[2]

Elevated LDL-C is an abnormality of cholesterol and/or fats in the blood.[3,4] Elevated LDL-C is recognized as a major risk factor for cardiovascular disease,[5,6] Canada's second leading killer.[7] Canadians with clinical atherosclerotic CVD and/or familial hypercholesterolemia (FH) are considered at high risk of cardiovascular disease[8,9] and lipid monitoring is important.[9,10] About 40 per cent of Canadians have high cholesterol,[10] and of patients who are considered at high risk for heart disease, 45 per cent are not meeting their target LDL-C levels.[11]

FH is an inherited condition caused by genetic mutations which lead to high levels of LDL-C at an early age,[12] and it is estimated that less than one per cent of people with FH (heterozygous and homozygous forms) in Canada are diagnosed.[13] HeFH prevalence in Canada is highest in Quebec affecting up to one in 270 people.[9]

In Phase 3 trials, adding Repatha to background lipid-lowering therapy that included statins resulted in consistent reductions in LDL-C levels with favourable effects on other lipid parameters. In patients with clinical atherosclerotic CVD or HeFH, Repatha reduced LDL-C by

up to 75 per cent compared with placebo.[2] In patients with HoFH, Repatha reduced LDL-C by approximately 32 per cent compared with placebo.[2]

“Repatha offers a new treatment option for patients who have elevated levels of cholesterol, despite using other lipid-lowering therapies, said Clive Ward-Able, Executive Director, Research and Development, Amgen Canada Inc. “This approval is an important step forward for Canadian patients for the treatment of high cholesterol levels, and marks a significant milestone for Amgen in our ongoing commitment to research in cardiovascular disease.”

“The approval of Repatha is an important development in the care of patients at high risk of cardiovascular disease who require additional LDL cholesterol lowering,” said Dr. G. B. John Mancini, Professor of Medicine at the University of British Columbia. “Improving the management of cholesterol for these patients is a serious concern for cardiologists, so this new option is welcome.”

Patients with genetically high cholesterol can have either one of two types of FH.[12] HeFH is the more common type of FH and occurs in approximately one in 500 Canadians.[9] It can cause LDL-C levels twice as high as normal (e.g., >4.9 mmol/L).[14] Individuals with HeFH have one altered copy of a cholesterol-regulating gene.[14] HoFH is the rare, more severe form, in which an individual has two altered copies of cholesterol-regulating genes (one from each parent).[12] It can cause LDL-C levels more than six times as high as normal (e.g., >13 mmol/L).[15] HoFH is rare, occurring in approximately one in a million individuals.[9] The frequency of HoFH is higher in founder populations, such as French Canadians[9] in Quebec where the prevalence is approximately one in 275,000.[16]

About Repatha™ (evolocumab)
Repatha (evolocumab) is a fully human monoclonal antibody that inhibits proprotein convertase subtilisin/kexin type 9 (PCSK9).[1] Repatha binds with high affinity 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.[2]

Important Safety Information[2]
Repatha is contraindicated in patients who are hypersensitive to Repatha or to any ingredient in the formulation or component of the container. Hypersensitivity reactions (e.g. 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.

The safety of Repatha was evaluated in approximately 6,700 patients with primary hyperlipidemia and mixed dyslipidemia. The most common adverse reactions of Repatha-treated patients were: nasopharyngitis, upper respiratory tract infection, influenza, back pain, arthralgia and nausea.

In a 52-week trial, the overall incidence of treatment emergent adverse events was comparable between the evolocumab QM (74.8%) and placebo (74.2%) treatment groups.

More information on Adverse Reactions may be found in the Repatha Product Monograph.

About PROFICIO: Repatha™ (evolocumab) Clinical Trial Program
PROFICIO, which stands for the Program to Reduce LDL-C and Cardiovascular Outcomes Following Inhibition of PCSK9 In Different POpulations, is a large and comprehensive clinical trial program evaluating Repatha in 22 clinical trials, with a combined planned enrollment of approximately 35,000 patients.

The Phase 3 program includes 16 trials to evaluate Repatha administered every two weeks and monthly in multiple patient populations, including in combination with statins in patients with hyperlipidemia (LAPLACE-2 and YUKAWA-2); in patients with hyperlipidemia who cannot tolerate statins (GAUSS-2 and GAUSS-3); as a stand-alone treatment in patients with hyperlipidemia (MENDEL-2); in patients whose elevated cholesterol is caused by genetic disorders called heterozygous (RUTHERFORD-2 and TAUSSIG) and homozygous (TESLA and TAUSSIG) familial hypercholesterolemia; the effects of Repatha on lipoprotein metabolism (FLOREY); and the administration of Repatha in statin-treated hyperlipidemic patients (THOMAS-1 and THOMAS-2).

Five ongoing studies in the Repatha Phase 3 program will further provide long-term safety and efficacy data. These include FOURIER (Further Cardiovascular OUtcomes Research with PCSK9 Inhibition in Subjects with Elevated Risk), which will assess whether treatment with Repatha in combination with statin therapy compared to placebo plus statin therapy reduces recurrent cardiovascular events in approximately 27,500 patients with cardiovascular disease; EBBINGHAUS (Evaluating PCSK9 Binding AntiBody Influence oN CoGnitive HeAlth in High CardiovascUlar Risk Subjects), which will evaluate the effect of Repatha on cognitive function in a subset of patients enrolled in FOURIER; OSLER-2 (Open Label Study of Long TERm Evaluation Against LDL-C Trial-2) in patients with high cholesterol who completed any of the Phase 3 studies; GLAGOV (GLobal Assessment of Plaque ReGression with a PCSK9 AntibOdy as Measured by IntraVascular Ultrasound), which will determine the effect of Repatha on coronary atherosclerosis in approximately 950 patients undergoing cardiac catheterization; and TAUSSIG (Trial Assessing Long Term USe of PCSK9 Inhibition in Subjects with Genetic LDL Disorders), which will assess the long-term safety and efficacy of Repatha on LDL-C in patients with severe familial hypercholesterolemia including patients with homozygous familial hypercholesterolemia. The DESCARTES (Durable Effect of PCSK9 Antibody CompARed wiTh PlacEbo Study) study, a long-term safety and efficacy trial in patients with hyperlipidemia at risk for cardiovascular disease, has completed.

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.[17] 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 pipeline consisting of several 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 Canada
As a leader in innovation, Amgen Canada understands the value of science. With main operations located in Mississauga, Ont.'s vibrant biomedical cluster, and its research facility in Burnaby, B.C., Amgen Canada has been an important contributor to advancements in science and innovation in Canada since 1991. The company contributes to the development of new therapies and new uses for existing medicines in partnership with many of Canada's leading health-care, academic, research, government and patient organizations. To learn more about Amgen Canada, visit www.amgen.ca.

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 September 15, 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 modelled 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 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 recently announced 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.

###

CONTACT:
Natasha Bond, Head of Corporate Affairs
Amgen Canada
905-285-3007
natasha.bond@amgen.com

References

1. Amgen Data on File, Investigator Brochure.
2. Repatha™ Product Monograph. Amgen Canada Inc. (September 2015).
3. World Health Organization. Quantifying Selected Major Risks to Health. In: The World Health Report 2002 - Reducing Risks, Promoting Healthy Life. Chapter 4: Geneva: 202:47-97.
4. Merck Manuals website. http://www.merckmanuals.com/professional/endocrine_and_metabolic_disorders/lipid_disorders/dyslipidemia.html. Accessed May 2015.
5. Heart and Stroke Foundation of Canada (2014). Getting your cholesterol in check.http://www.heartandstroke.com/site/c.ikIQLcMWJtE/b.3484027/k.8419/Heart_disease__High_blood_cholesterol.htm. Accessed August 2015.
6. World Health Organization. Global Status Report on Noncommunicable Diseases 2010. Geneva, 2011.
7. Statistics Canada (2014). The 10 leading causes of death, 2011. http://www.statcan.gc.ca/pub/82-625-x/2014001/article/11896-eng.htm. Accessed August 2015.
8. Genest J, McPherson R, Frohlich J, et al. 2009 Canadian Cardiovascular Society/Canadian guidelines for the diagnosis and treatment of dyslipidemia and prevention of cardiovascular disease in the adult – 2009 recommendations. Canadian Journal of Cardiology. 2009;25(10):567-579.
9. Genest J, Hegele R, Bergeron J, et al. Canadian Cardiovascular Society Position Statement on Familial Hypercholesterolemia. Canadian Journal of Cardiology. 2014;30: 1471-1481.
10. Statistics Canada (2013). Cholesterol levels of Canadians, 2009 to 2011. http://www.statcan.gc.ca/pub/82-625-x/2012001/article/11732-eng.htm. Accessed August 2015.
11. Goodman, S et al. Prevalence of dyslipidemia in statin-treated patients in Canada: Results of the DYSlipidemia International Study (DYSIS). Can J Cardiol 2010;26(9):e330-e335.
12. National Human Genome Research Institute. Learning About Familial Hypercholesterolemia. http://www.genome.gov/25520184. Accessed May 2015.
13. Nordestgaard BG, Chapman MJ, Humphries SE, et al. Familial Hypercholesterolaemia is Underdiagnosed and Undertreated in the General Population: Guidance for Clinicians to Prevent Coronary Heart Disease. Eur Heart J. 2013;34:3478-3490.
14. Hopkins PN, Toth PP, Ballantyne CM, et al. Familial Hypercholesterolemias: Prevalence, Genetics, Diagnosis and Screening Recommendations From the National Lipid Association Expert Panel on Familial Hypercholesterolemia. J Clin Lipid. 2011:5(3S):S9-S17.
15. Daniels SR, Samuel SG, de Ferranti SD. Pediatric Aspects of Familial Hypercholesterolemias: Recommendations from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. J Clin Lipid. 2011:5(3S):S30-S37.
16. Moorjani S, Roy M, Gagne C, et al. Homozygous familial hypercholesterolemia among French Canadians in Quebec province. Arteriosclerosis 1989;9:211-6.
17. World Health Organization. Cardiovascular diseases (CVDs) fact sheet. http://www.who.int/mediacentre/factsheets/fs317/en/. Accessed May 2015.