Amgen To Present New Data From The Repatha® (Evolocumab) Cardiovascular Outcomes Study At ESC Congress 2017

August 21, 2017

Analysis Evaluates the Effect of Repatha in More Than 5,000 Patients With a History of Stroke

THOUSAND OAKS, Calif., Aug. 21, 2017 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that new data from the Repatha® (evolocumab) clinical trial program, including three late-breaking scientific sessions, will be presented at the European Society of Cardiology (ESC) Congress 2017 in Barcelona, Spain, Aug. 26-30, 2017. New data includes additional efficacy and safety analyses from the Repatha cardiovascular outcomes trial (FOURIER) and the Repatha coronary intravascular ultrasound imaging trial (GLAGOV).

"Data from the Repatha clinical trial program continue to reinforce the value of this innovative medicine for patients at risk of a heart attack or stroke," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "We look forward to sharing the breadth of data demonstrating Repatha's ability to lower LDL cholesterol and reduce cardiovascular events, including the effect of Repatha in patients with a history of stroke."

Data from the Repatha cardiovascular outcomes trial assessing the effect of Repatha on cardiovascular outcomes in patients with a history of stroke will be presented in a late-breaking science session (Clinical Trial Update 2) along with a new analysis from the GLAGOV trial. A second analysis of the Repatha cardiovascular outcomes trial, assessing the efficacy and safety of achieving very low low-density lipoprotein cholesterol (LDL-C) levels with Repatha, will be presented in the late-breaking Clinical Trial Update 1 session.

Amgen-sponsored abstracts at ESC Congress 2017 include:

Repatha

Clinical

Late-Breaking Science Sessions

- **Clinical Efficacy and Safety of Achieving Very Low LDL-C Levels With the PCSK9 Inhibitor Evolocumab in the FOURIER Outcomes Trial**
  Clinical Trial Update 1, Monday, Aug. 28, 2:30 – 2:45 p.m. CEST
- **Effect of the PCSK9 Inhibitor, Evolocumab, on the Composition of Coronary Atherosclerosis: Insights on the GLAGOV Trial**
  Clinical Trial Update 2, Tuesday, Aug. 29, 4:45 – 5 p.m. CEST
- **Further Cardiovascular OUtcomes Research With PCSK9 Inhibition in Subjects With Elevated Risk (Focus on Cerebrovascular Disease)**
  Clinical Trial Update 2, Tuesday, Aug. 29, 5 – 5:15 p.m. CEST

Poster Sessions

- **Efficacy and Safety of Evolocumab Compared With Continued Lipoprotein Apheresis: Results of a Randomised, Controlled, Open-Label Study**
  Late-Breaking Science Posters, Sunday, Aug. 27, 8:30 a.m. – 6 p.m. CEST
  Moderated Session, 3:35 – 4:25 p.m. CEST
- **Evolocumab Treatment in Paediatric Patients With Homozygous Familial Hypercholesterolaemia: the Trial Assessing Long-Term Use of PCSK9 Inhibition in Subjects With Genetic LDL Disorders (TAUSSIG)**
  Rapid Fire Session, Lipid Lowering Therapy in Primary Cardiovascular Prevention, Monday, Aug. 28, 12:12 – 12:21 p.m. CEST
- **Evolocumab Lowers Plasma Lp(a) Concentration by Two Kinetic Modes of Action: From the FLOREY Study**
  Lipid Metabolism, Monday, Aug. 28, 8:30 a.m. – 12:30 p.m. CEST
  Moderated Session: 10:05 – 10:55 a.m. CEST
- **Is Lipoprotein(a) Metabolism Linked to the Transport and Catabolic Rates of Apolipoprotein B-100 Containing Lipoproteins?**
  Lipid Metabolism, Monday, Aug. 28, 8:30 a.m. – 12:30 p.m. CEST
  Moderated Session: 10:05 – 10:55 a.m. CEST

Observational Research

- **Changes in Lipid-lowering Therapy Prescription Patterns Following a Second Cardiovascular Disease Event**
  Lipid-lowering Therapy: Old Faces and New Issues, Saturday, Aug. 26, 11 a.m. – 4 p.m. CEST
  Moderated Session, 12:35 – 1:25 p.m. CEST
- **Evaluation of Statin Users, People With Hypercholesterolemia, and Cardiovascular Disease Patients in the Japan**

Medical Data Center Claims Database
Poster Session 1: Treatment of Dyslipidaemia, Saturday, Aug. 26, 11 a.m. – 4 p.m. CEST

- **Statin Use Among HIV-Infected Adults by Cardiovascular Disease Risk Status**
  Lipid-lowering Therapy: Old Faces and New Issues, Saturday, Aug. 26, 11 a.m. – 4 p.m. CEST
  Moderated Session, 12:35 – 1:25 p.m. CEST
- **Adherence to Intensive Medical Management in the Year Following Hospitalization for Myocardial Infarction**
  Poster Session 5: Prevention – Epidemiology, Monday, Aug. 28, 2 – 6 p.m. CEST
- **Characterizing Familial Hypercholesterolemia in an Electronic Health Record (EHR) Database**
  Poster Session 6: Lipids, Obesity and Metabolic Syndrome, Tuesday, Aug. 29, 8:30 a.m. – 12:30 p.m. CEST

Health Economics

- **Lack of Low-Density Lipoprotein Cholesterol (LDL-C) Goal Attainment Among High-Risk Patients Using High or Moderate Intensity Statin Therapy in Germany**
  Best Posters 3: Best Posters in New Targets in Cardiovascular Drug Assessment, Sunday, Aug. 27, 2 – 6 p.m. CEST
  Discussant Review, 3:35 – 4:25 p.m. CEST

Corlanor® (ivabradine)

Observational Research

- **Increased Heart Rate is Independently Associated With Worse Survival in Pediatric Patients with Dilated Cardiomyopathy: a Multicenter Study From the Pediatric Cardiomyopathy Registry**
  Contemporary Management of Risk Factors in Congenital Heart Disease, Sunday, Aug. 27, 8:57 - 9:06 a.m. CEST

Repatha Cardiovascular Outcomes (FOURIER) Study Design
The 27,564-patient Repatha cardiovascular outcomes study, FOURIER (Further Cardiovascular OUtcomes Research with PCSK9 Inhibition in Subjects with Elevated Risk), was a multinational Phase 3 randomized, double-blind, placebo-controlled trial, designed to evaluate whether treatment with Repatha in combination with statin therapy compared to placebo plus statin therapy reduces cardiovascular events. The primary endpoint was time to cardiovascular death, myocardial infarction, stroke, hospitalization for unstable angina, or coronary revascularization. The key secondary endpoint was the time to cardiovascular 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 atherosclerotic cardiovascular disease at more than 1,200 study locations around the world were randomized to receive Repatha subcutaneous 140 mg every two weeks or 420 mg monthly plus optimized statin dose; or placebo subcutaneous every two weeks or monthly plus optimized 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 1,630 patients experienced a key secondary endpoint.

GLAGOV Study Design
GLAGOV (GLobal Assessment of Plaque ReGression with a PCSK9 AntibOdy as Measured by IntraVascular Ultrasound) is a Phase 3, multicenter, double-blind, randomized, placebo-controlled trial designed to evaluate the effect of Repatha on the change in burden of coronary artery disease (CAD) in 968 patients undergoing clinically indicated coronary angiogram and on optimized background statin therapy.

Patients were required to have been treated with a stable statin dose for at least four weeks and to have a LDL-C ≥80 mg/dL or between 60 and 80 mg/dL with one major cardiovascular risk factor (defined as non-coronary atherosclerotic vascular disease, myocardial infarction or hospitalization for unstable angina in the preceding two years or type 2 diabetes mellitus) or three minor cardiovascular risk factors (defined as current cigarette smoking, hypertension, low levels of HDL cholesterol, family history of premature coronary heart disease, high sensitivity C-reactive protein (hs-CRP) ≥2 mg/L or age ≥50 years in men and 55 years in women).

Patients were randomized 1:1 into two treatment groups to either receive monthly Repatha 420 mg or placebo subcutaneous injections. Optimized statin therapy was defined as at least atorvastatin 20 mg daily or equivalent, titrated to achieve LDL-C reduction per regional guidelines. Highly effective statin therapy (equivalent to atorvastatin 40 mg daily or higher) was recommended for all patients. Those patients with LDL-C >100 mg/dL not taking highly effective statin therapy, required investigators' attestation as to why such doses were not appropriate. The primary endpoint was change in percent atheroma volume (PAV) from baseline to week 78 compared to placebo, as determined by intravascular ultrasound (IVUS). IVUS is a high-resolution imaging tool that allows for the quantification of coronary atheroma in the coronary arteries.

Secondary endpoints included PAV regression (any reduction from baseline); change in total atheroma volume (TAV) from baseline to week 78; and regression (any reduction from baseline) in TAV.

About Repatha® (evolocumab)
Repatha® (evolocumab) 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.[1]

Repatha is approved in more than 50 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.

U.S. Repatha Indication
Repatha® is indicated as an adjunct to diet and:

- Maximally tolerated statin therapy for treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C)
- 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 effect of Repatha® on cardiovascular morbidity and mortality has not been determined.

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

The safety and effectiveness of Repatha® have not been established 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®.

Allergic reactions: 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.

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

In a 52-week trial, adverse reactions led to discontinuation of treatment in 2.2% of Repatha®-treated patients and 1% of placebo-treated patients. The most common adverse reaction that led to Repatha® treatment discontinuation and occurred at a rate greater than placebo was myalgia (0.3% versus 0% for Repatha® and placebo, respectively).

Adverse 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. The proportions of patients who discontinued treatment due to local injection site reactions in Repatha®-treated patients and placebo-treated patients were 0.1% and 0%, respectively.

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%).

Neurocognitive events were reported in less than or equal to 0.2% in Repatha®-treated and placebo-treated patients.

In a pool of placebo- and active-controlled trials, as well as open-label extension studies that followed them, a total of 1,988 patients treated with Repatha® had at least one LDL-C value <25 mg/dL. Changes to background lipid-altering therapy were not made in response to low LDL-C values, and Repatha® dosing was not modified or interrupted on this basis. Although adverse consequences of very low LDL-C were not identified in these trials, the long-term effects of very low levels of LDL-C induced by Repatha® are unknown.

Musculoskeletal adverse reactions were reported in 14.3% of Repatha®-treated patients and 12.8% of placebo-treated patients. The most common adverse reactions that occurred at a rate greater than placebo were back pain (3.2% versus 2.9% for Repatha® and placebo, respectively), arthralgia (2.3% versus 2.2%), and myalgia (2.0% versus 1.8%).

Homozygous Familial Hypercholesterolemia (HoFH): In 49 patients with homozygous familial hypercholesterolemia studied in a 12-week, double-blind, randomized, placebo-controlled trial, 33 patients received 420 mg of Repatha® subcutaneously once monthly. The adverse reactions that occurred in at least 2 (6.1%) Repatha®-treated patients and more frequently than in placebo-treated patients, included upper respiratory tract infection (9.1% versus 6.3%), influenza (9.1% versus 0%), gastroenteritis (6.1% versus 0%), and nasopharyngitis (6.1% versus 0%).

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.

Important EU Product Information
In Europe Repatha is approved for use in:

Hypercholesterolemia and mixed dyslipidemia
Repatha is indicated in adults with primary hypercholesterolemia (heterozygous familial 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.

Homozygous familial hypercholesterolemia
Repatha is indicated in adults and adolescents aged 12 years and over with homozygous familial hypercholesterolemia in combination with other lipid-lowering therapies.

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

Posology
Primary hypercholesterolemia and mixed dyslipidemia in adults
The recommended dose of Repatha is either 140 mg every two weeks or 420 mg once monthly; both doses are clinically equivalent.

Homozygous familial hypercholesterolemia 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.

Important 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.

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 month.

About Corlanor® (ivabradine)
Corlanor® (ivabradine) blocks the hyperpolarization-activated cyclic nucleotide-gated (HCN) channel responsible for the cardiac pacemaker, which regulates heart rate. Corlanor reduces the spontaneous pacemaker activity of the cardiac sinus node by selectively inhibiting the I_f current ("funny" current) to slow the heart rate with no effect on ventricular repolarization and no effects on myocardial contractility.[2] Corlanor was developed by Servier. Through a collaboration with Servier, Amgen has rights to commercialize Corlanor in the U.S.

U.S. Corlanor Indication:
Corlanor® is indicated to reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction ≤ 35%, who are in sinus rhythm with resting heart rate ≥ 70 beats per minute (bpm) and either are on maximally tolerated doses of beta blockers or have a contraindication to beta blocker use.

Important U.S. Safety Information
Contraindications: Corlanor® is contraindicated in patients with acute decompensated heart failure, blood pressure < 90/50 mmHg, sick sinus syndrome, sinoatrial block, 3rd degree atrioventricular (AV) block (unless a functioning demand pacemaker is present), a resting heart rate < 60 bpm prior to treatment, severe hepatic impairment, pacemaker dependence (heart rate maintained exclusively by the pacemaker) and concomitant use of strong cytochrome P450 3A4 (CYP3A4) inhibitors.

- **Fetal Toxicity:** Corlanor® may cause fetal toxicity when administered to a pregnant woman.
- **Atrial Fibrillation:** Corlanor® increases the risk of atrial fibrillation. The rate of atrial fibrillation in patients treated with Corlanor® compared to placebo was 5% vs. 3.9% per patient-year, respectively.
- **Bradycardia and Conduction Disturbances:** Bradycardia, sinus arrest and heart block have occurred with Corlanor®. Bradycardia may increase the risk of QT prolongation which may lead to severe ventricular arrhythmias, including torsades de pointes, especially in patients with risk factors such as use of QTc prolonging drugs. Concurrent use of verapamil or diltiazem also increases Corlanor® exposure and should be avoided. Avoid use of Corlanor® in patients with 2nd degree atrioventricular block unless a functioning demand pacemaker is present.
- **Adverse Reactions:** The most common adverse drug reactions reported at least 1% more frequently with Corlanor® than placebo and that occurred in more than 1% of patients treated with Corlanor® were bradycardia (10% vs. 2.2%), hypertension or increased blood pressure (8.9% vs. 7.8%), atrial fibrillation (8.3% vs. 6.6%), and luminous phenomena (phosphenes) or visual brightness (2.8% vs. 0.5%). In postmarketing experience, torsades de pointes has been observed.

Please contact Amgen Medinfo at 800-77-AMGEN (800-772-6436) regarding Corlanor availability or find out more information, including full Prescribing Information and Medication Guide at www.amgen.com and www.Corlanor.com.

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.[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 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 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 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 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 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 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 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. 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 acquire other companies or products and to integrate the operations of companies we have acquired may not be successful. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all. We are increasingly dependent on information technology systems, infrastructure and data security. Our stock price is volatile and may be affected by a number of events. 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.

The scientific information discussed in this news release relating to new indications is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration or European Commission 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.

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2. Corlanor® U.S. Prescribing Information. Amgen.
3. World Health Organization. Cardiovascular diseases (CVDs) fact sheet. http://www.who.int/mediacentre/factsheets/fs317/en/. Accessed July 2017.

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