Amgen Issues Voluntary Recall of Aranesp® (darbepoetin alfa) (500 mcg) Prefilled Syringes in Several Countries Outside of the United States Due to the Presence of Visible Particulates

August 13, 2014

THOUSAND OAKS, Calif., Aug. 13, 2014 /PRNewswire/ -- Amgen (NASDAQ:AMGN) initiated a voluntary recall on June 26, 2014 for nine packaged lots of Aranesp® (darbepoetin alfa) (500 mcg) prefilled syringes from non-U.S. distributors, wholesalers and a number of hospital pharmacies due to the potential presence of cellulose and/or polyester particles observed in a small number of syringes during a routine quality examination. Lots 1042847, 1044141A, 1044141C, 1044141D, 1046891A, 1046891B, 1047394A, 1047622A, and 1047996A are being recalled as a precautionary measure. To date, there have been no complaints or adverse events reported that can be attributed to the presence of these particles. Evaluations by Amgen found a very low potential to impact patients who may have received the affected product.

The U.S. Food and Drug Administration (FDA) has determined that health implications related to particles, depending on the route of administration, would vary depending on the amount of particulate matter injected into the patient, the size of the particles, the patient's underlying medical condition, and the presence of a right-to-left cardiac shunt. The presence of particulate foreign matter may elicit inflammatory and allergic responses, both chronic and acute, and may be life-threatening.

In the U.S., Aranesp is indicated for the treatment of anemia associated with chronic renal failure, including patients on dialysis and patients not on dialysis or in patients with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy. The potentially impacted product is Aranesp 500mcg prefilled syringes which were distributed outside of the United States.

A single lot of Aranesp was packaged for different countries into nine packaged lots (lot numbers: 1042847, 1044141A, 1044141C, 1044141D, 1046891A, 1046891B, 1047394A, 1047622A, and 1047996A). Aranesp distributed in the U.S. is not impacted by this recall nor is product supply impacted. The impacted syringes were distributed in Belgium, Denmark, Finland, France, Ireland, Italy, Kuwait, Luxemburg, Russia, Saudi Arabia, Slovenia, Sweden, Switzerland and UK. Notifications to the appropriate regulatory authorities have been completed.

Consumers in the U.S. who have questions regarding this recall can contact Amgen at 1-800-77-AMGEN to arrange for the prompt return of the product (open 24 hours per day, 7 days per week).

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This recall in non-U.S. jurisdictions is being conducted with the knowledge of the FDA.

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.

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 August 13, 2014, 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. Cost saving initiatives may result in us incurring impairment or other related charges on our assets. We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our recently announced restructuring plans. 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 preliminary and investigative. 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.

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