Amgen And DaVita Enter Into New Sourcing And Supply Agreement

January 9, 2017

THOUSAND OAKS, Calif., Jan. 9, 2017 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced it has entered into a six-year Sourcing and Supply Agreement with DaVita Inc. This is a continuation of Amgen's long-term relationship with DaVita that is focused on serving dialysis patients.

Under the terms of the new agreement, Amgen will supply DaVita with EPOGEN® (epoetin alfa) and Aranesp® (darbepoetin alfa) in amounts necessary to meet a specified annual percentage of DaVita's and its affiliates' requirements for erythropoiesis-stimulating agents used in providing dialysis services in the United States and Puerto Rico. The percentage varies during the term of the new agreement from Jan. 6, 2017, through Dec. 31, 2022, but in each year is at least 90 percent. The new agreement will replace the Sourcing and Supply Agreement dated Nov. 15, 2011, between Amgen and DaVita that would have expired on Dec. 31, 2018.

About EPOGEN® (epoetin alfa) and Aranesp® (darbepoetin alfa) in the U.S.

EPOGEN® (epoetin alfa) is indicated for the treatment of anemia due to chronic kidney disease (CKD) in patients on dialysis to decrease the need for red blood cell (RBC) transfusion.

Aranesp® (darbepoetin alfa) is indicated for the treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and patients not on dialysis.
Limitations of Use:
- Aranesp and EPOGEN have not been shown to improve quality of life, fatigue, or patient well-being.
- Aranesp and EPOGEN are not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.

EPOGEN and Aranesp Important Safety Information in the U.S.

WARNING: ESAs INCREASE THE RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, THROMBOSIS OF VASCULAR ACCESS AND TUMOR PROGRESSION OR RECURRENCE
Chronic Kidney Disease:

- **In controlled trials, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered erythropoiesis-stimulating agents (ESAs) to target a hemoglobin level of greater than 11 g/dL.**
- **No trial has identified a hemoglobin target level, ESA dose, or dosing strategy that does not increase these risks.**
- **Use the lowest Aranesp® or EPOGEN® dose sufficient to reduce the need for red blood cell (RBC) transfusions.**

Cancer:

- **ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in clinical studies of patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.**
- **Because of these risks, prescribers and hospitals must enroll in and comply with the ESA APPRISE Oncology Program to prescribe and/or dispense Aranesp® or EPOGEN® to patients with cancer. To enroll in the ESA APPRISE Oncology Program, visit www.esa-apprise.com or call 1-866-284-8089 for further assistance.**
- **To decrease these risks, as well as the risk of serious cardiovascular and thromboembolic reactions, use the lowest dose needed to avoid RBC transfusions.**
- **Use ESAs only for anemia from myelosuppressive chemotherapy.**
- **ESAs are not indicated for patients receiving myelosuppressive chemotherapy when the anticipated outcome is cure.**
- **Discontinue following the completion of a chemotherapy course.**

Perisurgery (EPOGEN®):

- **Due to increased risk of Deep Venous Thrombosis (DVT), DVT prophylaxis is recommended.**

- Aranesp® (darbepoetin alfa) and EPOGEN® (epoetin alfa) are contraindicated in patients with:
  - Uncontrolled hypertension
  - Pure red cell aplasia (PRCA) that begins after treatment with Aranesp®, EPOGEN®, or other erythropoietin protein drugs
  - Serious allergic reactions to Aranesp® or EPOGEN®
- EPOGEN® from multidose vials contains benzyl alcohol and is contraindicated in neonates, infants, pregnant women, and nursing mothers.
- Use caution in patients with coexistent cardiovascular disease and stroke.
- Patients with CKD and an insufficient hemoglobin response to ESA therapy may be at even greater risk for cardiovascular

reactions and mortality than other patients. A rate of hemoglobin rise of > 1 g/dL over 2 weeks may contribute to these risks.

- In controlled clinical trials, ESAs increased the risk of death in patients undergoing coronary artery bypass graft surgery (CABG) and the risk of deep venous thrombosis (DVT) in patients undergoing orthopedic procedures.
- Control hypertension prior to initiating and during treatment with Aranesp® or EPOGEN®.
- Aranesp® and EPOGEN® increase the risk of seizures in patients with CKD. Monitor patients closely for new-onset seizures, premonitory symptoms, or change in seizure frequency.
- For lack or loss of hemoglobin response to Aranesp® or EPOGEN®, initiate a search for causative factors. If typical causes of lack or loss of hemoglobin response are excluded, evaluate for PRCA.
- Cases of PRCA and of severe anemia, with or without other cytopenias that arise following the development of neutralizing antibodies to erythropoietin have been reported in patients treated with Aranesp® or EPOGEN®.
    - This has been reported predominantly in patients with CKD receiving ESAs by subcutaneous administration.
    - PRCA has also been reported in patients receiving ESAs for anemia related to hepatitis C treatment (an indication for which Aranesp® and EPOGEN® are not approved).
    - If severe anemia and low reticulocyte count develop during treatment with Aranesp® or EPOGEN®, withhold Aranesp® or EPOGEN® and evaluate patients for neutralizing antibodies to erythropoietin.
    - Permanently discontinue Aranesp® or EPOGEN® in patients who develop PRCA following treatment with Aranesp®, EPOGEN®, or other erythropoietin protein drugs. Do not switch patients to other ESAs.
- Serious allergic reactions, including anaphylactic reactions, angioedema, bronchospasm, skin rash, and urticaria may occur with Aranesp® or EPOGEN®. Immediately and permanently discontinue Aranesp® or EPOGEN® if a serious allergic reaction occurs.
- Adverse reactions (≥ 10%) in Aranesp® clinical studies in patients with CKD were hypertension, dyspnea, peripheral edema, cough, and procedural hypotension.
- Adverse reactions (≥ 5%) in EPOGEN® clinical studies in patients with CKD were hypertension, arthralgia, muscle spasm, pyrexia, dizziness, medical device malfunction, vascular occlusion, and upper respiratory tract infection.

Please see EPOGEN® full Prescribing Information, including **Boxed WARNINGS**, and Medication Guide.

Please see Aranesp® full Prescribing Information, including **Boxed WARNINGS**, and Medication Guide.

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 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 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. 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 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. 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 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.

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