Amgen Acquires Filgrastim Franchise Rights From Roche In 100 Markets

October 22, 2013

THOUSAND OAKS, Calif., Oct. 22, 2013 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that it has entered into a definitive agreement with F. Hoffmann-La Roche ("Roche") to acquire Roche's rights to filgrastim and pegfilgrastim in approximately 100 markets, effective Jan. 1, 2014.

Roche has held the rights to filgrastim and pegfilgrastim under license from Kirin-Amgen, Inc. (a joint venture between Amgen and Kirin Holdings Co. Limited, of Japan) in Eastern Europe, Latin America, Asia, the Middle East and Africa since 1989. The franchise generated approximately $200 million in sales in these territories in 2012.

Filgrastim and pegfilgrastim are white blood cell boosting therapeutics used to reduce the risk of infection in patients receiving chemotherapy. They are marketed by Amgen in the United States and Europe under the trade names NEUPOGEN® and Neulasta®, respectively.

"This agreement will enable Amgen to reach more patients around the world with two of our innovative medicines," said Robert A. Bradway, chairman and chief executive officer of Amgen. "The transaction will also allow us to build experience and capacity in countries that will be important in accelerating future growth of Amgen's pipeline products."

Amgen anticipates this deal will be accretive starting in 2014.

Amgen will begin distributing and selling product as soon as practical in countries where the Company has an existing commercial presence. In countries where Amgen does not have a presence, Roche or its distributors will continue to sell and distribute the products for an interim transition period.

"Amgen and Roche will work closely to ensure a seamless transition of the business, marketing authorizations, and most importantly, product supply to the physicians and patients that rely on these important medicines," said Anthony C. Hooper, executive vice president, Global Commercial Operations of Amgen. "Amgen is pleased to have the opportunity to prevent patients receiving myelosuppressive chemotherapy from developing febrile neutropenia in additional markets around the world."

Amgen has grown to be the world's largest independent biotechnology company reaching millions of patients around the world. A worldwide leader in biologics manufacturing, Amgen has an outstanding track record of reliably delivering high-quality medicines to patients who need them.

Kyowa Hakko Kirin Co., Ltd. of Japan will continue to retain product rights and market filgrastim and pegfilgrastim in some selected Asian territories, including China and Japan.

About Neulasta and NEUPOGEN

Neulasta (pegfilgrastim) is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia. Neulasta is not indicated for the mobilization of peripheralblood progenitor cells for hematopoietic stem cell transplantation.

NEUPOGEN (filgrastim) is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a significant incidence of severe neutropenia with fever. A complete blood count and platelet count should be obtained prior to chemotherapy, and twice per week during NEUPOGEN therapy to avoid leukocytosis and to monitor the neutrophil count.

Important Safety Information

Do not administer Neulasta to patients with a history of serious allergic reactions to pegfilgrastim or filgrastim. NEUPOGEN is contraindicated in patients with known hypersensitivity to E coli-derived proteins, filgrastim, or any component of the product.

Serious allergic reactions, including anaphylaxis, can occur in patients receiving Neulasta or NEUPOGEN. Reported events have occurred with initial and/or subsequent treatment. Allergic reactions can recur within days after the discontinuation of initial anti-allergic treatment. Permanently discontinue Neulasta or NEUPOGEN in patients with serious allergic reactions.

Splenic rupture, including fatal cases, can occur following the administration of Neulasta and NEUPOGEN. Evaluate for an enlarged spleen or splenic rupture in patients who report left upper abdominal or shoulder pain after receiving Neulasta or NEUPOGEN.

Acute respiratory distress syndrome (ARDS) can occur in patients receiving Neulasta or NEUPOGEN. Evaluate patients who develop fever and lung infiltrates or respiratory distress after receiving Neulasta or NEUPOGEN for ARDS. Discontinue Neulasta or NEUPOGEN in patients with ARDS.

Alveolar hemorrhage, manifesting as pulmonary infiltrates and hemoptysis requiring hospitalization, has been reported in healthy donors undergoing peripheral blood progenitor cell mobilization, an unapproved use of NEUPOGEN. Hemoptysis resolved with discontinuation of NEUPOGEN.

Severe sickle cell crises can occur in patients with sickle cell disorders receiving Neulasta. Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disorders receiving filgrastim, the parent compound of pegfilgrastim.

Thrombocytopenia has been reported commonly in patients receiving NEUPOGEN. Platelet counts should be monitored closely.

The granulocyte colony-stimulating factor (G-CSF) receptor, through which pegfilgrastim and filgrastim act, has been found on tumor cell lines. The possibility that pegfilgrastim and filgrastim act as growth factors for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which they are not approved, cannot be excluded.

Bone pain and pain in extremity occurred at a higher incidence in Neulasta-treated patients as compared with placebo-treated patients. In clinical trials involving NEUPOGEN, bone pain was the most frequently reported adverse event.

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 involve significant risks and uncertainties, including those discussed below and others that can be found in our Form 10-K for the year ended Dec. 31, 2012, and in any subsequent periodic reports on Form 10-Q and Form 8-K. 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. The Company's results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments (domestic or foreign) involving current and future products, sales growth of recently launched products, competition from other products (domestic or foreign), and difficulties or delays in manufacturing our products. In addition, sales of our products are affected by 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. 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. 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. 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, we compete with other companies with respect to some of our marketed products as well as for the discovery and development of new products. Discovery or identification of new product candidates cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate will be successful and become a commercial product. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. 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.

CONTACT: Amgen, Thousand Oaks
Christine Regan, 805-447-5476 (media)
Arvind Sood, 805-447-1060 (investors)

(Logo: http://photos.prnewswire.com/prnh/20081015/AMGENLOGO)

SOURCE Amgen