Amgen Launches Neulasta® (pegfilgrastim) Onpro® NARRATIVES

April 18, 2017

Online News Resource Highlights Importance of Patient and Care Team Dialogue

THOUSAND OAKS, Calif., April 18, 2017 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced the launch of Neulasta® (pegfilgrastim) Onpro® NARRATIVES, an online media resource about the value of a cancer care team that provides comprehensive support for patients receiving strong chemotherapy. Intended to support conversations between cancer patients undergoing strong chemotherapy and their healthcare team about potential risk for infection due to a low white blood cell count, Neulasta Onpro NARRATIVES shares personal cancer stories as well as educational materials.

Experience the interactive Multimedia News Release here: http://www.multivu.com/players/English/7811431-neulasta-pegfilgrastim-onpro-narratives/

"Getting the breast cancer diagnosis was terrifying and unbelievable," said Natalie M., a breast cancer patient from Huntington Beach, Calif. "But once I got over the shock, I made sure I had the right team around me, including an oncologist and nursing staff I trusted to help guide me through my cancer journey."

After identifying Natalie was at risk for infection due to strong chemotherapy, her oncologist, Dr. John S. Link in Orange County, Calif., recommended she take Neulasta. When discussing options for Neulasta delivery, her nurse – Linda Buck, MSN, ANP-C, OCN – suggested Natalie try Neulasta Onpro because it could be applied the same day as her chemotherapy treatment and was designed to automatically deliver the dose of Neulasta the next day.[1]

On Neulasta Onpro NARRATIVES, Dr. Link and Nurse Buck share their personal experience working together to care for people going through strong chemotherapy and identify those who may be at risk for infection, and specifically describe how they cared for Natalie through her very personal cancer journey.

In addition to the personal stories, Neulasta Onpro NARRATIVES provides tips for initiating the important discussion between patients and their cancer care team, along with other educational resources. Resources on Neulasta Onpro NARRATIVES are intended to help raise awareness of the risk for infection due to strong chemotherapy and encourage patients to discuss the potential risk with their healthcare professional.

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

In a pivotal clinical trial, in patients with nonmyeloid malignancies undergoing myelosuppressive chemotherapy associated with a clinically significant incidence of febrile neutropenia, treatment with Neulasta was shown to significantly reduce the incidence of febrile neutropenia.

Neulasta is administered by manual injection and is also available via the Neulasta® Onpro® kit, which was approved by the FDA in 2014 and includes a specially designed, single-use prefilled syringe co-packaged with an on-body injector for Neulasta.

For more information about Neulasta, visit www.Neulasta.com and www.NeulastaHCP.com.

Important Safety Information Regarding Neulasta®

Contraindication
Do not administer Neulasta® to patients with a history of serious allergic reactions to pegfilgrastim or filgrastim.

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

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

Serious Allergic Reactions
Serious allergic reactions, including anaphylaxis, can occur in patients receiving Neulasta®. The majority of reported events occurred upon initial exposure. Allergic reactions, including anaphylaxis, can recur within days after the discontinuation of initial anti-allergic treatment. Permanently discontinue Neulasta® in patients with serious allergic reactions.

Allergies to Acrylics
The on-body injector for Neulasta® uses acrylic adhesive. For patients who have reactions to acrylic adhesives, use of this product may result in a significant reaction.

Use in Patients with Sickle Cell Disorders
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.

Glomerulonephritis
Glomerulonephritis has been reported in patients receiving Neulasta®. The diagnoses were based upon azotemia, hematuria (microscopic and macroscopic), proteinuria, and renal biopsy. Generally, events of glomerulonephritis resolved after withdrawal of Neulasta®. If glomerulonephritis is suspected, evaluate for cause. If causality is likely, consider dose-reduction or interruption of Neulasta®.

Leukocytosis
White blood cell counts of 100 x 10^9/L or greater have been observed in patients receiving pegfilgrastim. Monitoring of CBCs during pegfilgrastim therapy is recommended.

Capillary Leak Syndrome
Capillary leak syndrome has been reported after granulocyte colony-stimulating factor (G-CSF) administration, including Neulasta®, and is characterized by hypotension, hypoalbuminemia, edema, and hemoconcentration. Episodes vary in frequency, severity and may be life-threatening if treatment is delayed. Patients who develop symptoms of capillary leak syndrome should be closely monitored and receive standard symptomatic treatment, which may include a need for intensive care.

Potential for Tumor Growth Stimulatory Effects on Malignant Cells
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 acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which pegfilgrastim is not approved, cannot be excluded.

The most common adverse reactions (≥ 5% difference in incidence) in placebo-controlled clinical trials are bone pain and pain in extremity.

Please see additional Neulasta® Safety Information, by visiting www.amgen.com/medpro/products.html.

Please see the Neulasta Full Prescribing Information by clicking here.

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.

About Amgen's Commitment to Oncology
Amgen Oncology is committed to helping patients take on some of the toughest cancers, such as those that have been resistant to drugs, those that progress rapidly through the body and those where limited treatment options exist. Amgen's supportive care treatments help patients combat certain side effects of strong chemotherapy, and our targeted medicines and immunotherapies focus on more than a dozen different malignancies, ranging from blood cancers to solid tumors. With decades of experience providing therapies for cancer patients, Amgen continues to grow its portfolio of innovative and biosimilar oncology medicines.

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. 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. 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. 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.

References:

1. Neulasta® (pegfilgrastim) prescribing information, Amgen Inc., v20, 12/2016.

USA-003-038985

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/amgen-launches-neulasta-pegfilgrastim-onpro-narratives-300441301.html

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