**Neulasta® (pegfilgrastim) Fact Sheet**

Neulasta® (pegfilgrastim) is a prescription medicine used to help reduce the chance of infection due to a low white blood cell count, in people with certain types of cancer (non-myeloid), who receive anti-cancer medicines (chemotherapy) that can cause fever and low blood cell count. Strong chemotherapy can reduce the white blood cell count, which weakens the immune system and can lead to an increased risk of infection. Neulasta® works by boosting the number of infection-fighting white blood cells called neutrophils, which strengthen the immune system.

Neulasta® is a biologic therapy, or genetically-engineered protein, produced in living cells. Neulasta® is similar to a protein made by the body and may also be called a white blood cell booster because it causes the body to make more white blood cells. This helps increase the natural defenses against infection.

Pegfilgrastim is marketed by Amgen as Neulasta® in the United States, Canada, several European countries and Australia. Pegfilgrastim is also marketed by Amgen partners in numerous other countries. Neulasta® was approved by the U.S. Food and Drug Administration (FDA) in 2002.

**How It Works**

Neulasta® was engineered to mimic a protein naturally produced in the body known as granulocyte colony-stimulating factor (G-CSF). G-CSF binds to receptors on hematopoietic cells, young stem cells within the bone marrow, to stimulate growth of neutrophils. By working like this natural protein, Neulasta® signals the growth of these new white blood cells, which helps protect against the risk of infection following strong chemotherapy. Neulasta® is a long-acting form of G-CSF that can stay in the body for longer periods of time than the natural protein. Higher doses of Neulasta® are associated with a longer lasting presence in circulation. Neulasta® is also self-regulating, and begins to clear from circulation as more neutrophils are formed.

**Important Safety Information**

**Who should not take Neulasta®?**

Do not take Neulasta® if you have had a serious allergic reaction to Neulasta® (pegfilgrastim) or to NEUPOGEN® (filgrastim).

**What should I tell my health care provider before taking Neulasta®?**

Tell your healthcare provider if you:

- Have sickle cell trait or sickle cell disease
- Have had severe skin reactions to acrylic adhesives
- Are allergic to latex
- Have problems with your kidneys
- Have any other medical problems
- Are pregnant or plan to become pregnant. It is not known if Neulasta® may harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if Neulasta® passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
**Dosing and Administration**

The recommended dosage of Neulasta® is a single, subcutaneous injection of 6 mg, administered once-per-chemotherapy cycle in adults. Neulasta® should be administered no less than 24 hours after strong chemotherapy and no sooner than 14 days prior to the next treatment cycle.1

Neulasta® 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®.1,3 The Neulasta® Onpro® kit enables healthcare providers (HCP) to initiate administration of Neulasta® on the same day as chemotherapy, with delivery of the patient’s full dose of Neulasta® the day following chemotherapy administration, consistent with the Neulasta® prescribing information.1 The On-body Injector is filled by an HCP with the dose of Neulasta® and is applied to the patient’s skin.1 The On-body Injector provides visual and audible notifications for key steps throughout the Neulasta® delivery process.8

**Study Results of Interest**

**Pivotal Phase 3 Clinical Trials**

A Phase 3, placebo-controlled trial showed that Neulasta® helped to protect against the risk of infection with fever, also called febrile neutropenia (FN) in patients undergoing strong chemotherapy treatment.7,8 The trial evaluated 928 breast cancer patients undergoing treatment with a moderately strong chemotherapy regimen. One group of patients, called the study group, received Neulasta®, while the other group of patients, called the placebo group, did not receive Neulasta®. The study results, published in the *Journal of Clinical Oncology*, demonstrated:

- Neulasta® given during the first- and subsequent-chemotherapy cycles markedly reduced FN risk, including a 94 percent reduction in the cases of FN (17 percent placebo group vs. 1 percent study group), a 93 percent decrease in the number of patients hospitalized for FN and associated infections (14 percent vs. 1 percent), and an 80 percent decrease in the use of intravenous (IV) antibiotics (10 percent vs. 2 percent).8

**Neulasta® Onpro® Kit Studies**

Results from a study evaluating how Neulasta® moves through the body demonstrated that Neulasta® entered the bloodstream and circulated similarly whether it was delivered by the On-body Injector for Neulasta®, as part of the Neulasta® Onpro® kit, or delivered via a manual prefilled syringe.1

**Important Safety Information, continued**

What are possible serious side effects of Neulasta®?

- **Spleen Rupture.** Your spleen may become enlarged and can rupture while taking Neulasta®. A ruptured spleen can cause death. Call your doctor right away if you have pain in the left upper stomach area or left shoulder tip area. This pain could mean your spleen is enlarged or ruptured.

- **A serious lung problem called Acute Respiratory Distress Syndrome (ARDS).** Call your healthcare provider or get emergency medical help right away if you get any of these symptoms of ARDS: fever, shortness of breath, trouble breathing, or a fast rate of breathing.

- **Serious Allergic Reactions.** Get emergency medical help right away if you get any of these symptoms of a serious allergic reaction with Neulasta®: shortness of breath, wheezing, dizziness, swelling around the mouth or eyes, fast pulse, sweating, and hives.

**If you have an allergic reaction during the delivery of Neulasta®, remove the On-body Injector for Neulasta® by grabbing the edge of the adhesive pad and peeling off the On-body Injector. Get emergency medical help right away.**

- **Sickle Cell Crises.** Severe sickle cell crises, and sometimes death, can happen in people with sickle cell trait or disease who receive filgrastim, a medicine similar to Neulasta®.

- **Kidney injury (glomerulonephritis).** Kidney injury has been seen in patients who received Neulasta®. You should notify your healthcare provider right away if you experience puffiness in your face or ankles, blood in your urine or brown colored urine or you notice you urinate less than usual.

- **Increased white blood cell count (leukocytosis).** Your doctor will check your blood during treatment with Neulasta®.

- **Capillary Leak Syndrome.** Neulasta® can cause fluid to leak from blood vessels into your body’s tissues. This condition is called “Capillary Leak Syndrome” (CLS). CLS can quickly cause you to have symptoms that may become life-threatening. Get emergency medical help right away if you develop any of the following symptoms:
  - swelling or puffiness and are urinating less often
  - trouble breathing
  - swelling of your stomach area (abdomen) and feeling of fullness
  - dizziness or feeling faint
• a general feeling of tiredness

The most common side effect of Neulasta® is pain in the bones and in your arms and legs.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Neulasta®. Call your doctor for medical advice about side effects. You may report negative side effects to the FDA at 1-800-FDA-1088.

For more information about Neulasta®, talk with your healthcare provider or pharmacist; go to www.neulasta.com, or call 1-844-696-3852 (1-844-MYNEULASTA).

Please see Neulasta® Patient Information.

Commitment to Patient Access
Amgen is committed to helping clinically appropriate patients access to Neulasta®. For more information, visit www.amgenassist.com

Media Inquiries
Kristen Davis, 805-447-3008 (Media)
Kristen Neese, 805-313-8267 (Media)
Arvind Sood, 805-447-1060 (Investors)

Additional Information
For further information, visit www.neulasta.com or www.amgen.com.

Forward-Looking Statements
This fact sheet 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 fact sheet 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 to the extent we enter into 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 fact sheet relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration for the products. The products are not approved for the investigational use(s) discussed in this fact sheet, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses.

References
1. Neulasta® (pegfilgrastim) Prescribing Information, Amgen.