Pfizer Logo

FDA Approves Pfizer's Oncology Supportive Care Biosimilar, NYVEPRIA™ (pegfilgrastim-apgf)

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NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced the United States (U.S.) Food and Drug Administration (FDA) has approved NYVEPRIA™ (pegfilgrastim-apgf), a biosimilar to Neulasta® (pegfilgrastim).[1] NYVEPRIA is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.[2]

"The FDA approval of NYVEPRIA is a positive step that could both enable cost savings and increase access to an important treatment option," said Andy Schmeltz, Global President, Pfizer Oncology. "We are proud to add this new, long-acting supportive care option to our robust portfolio, now with six FDA-approved oncology biosimilars including three specifically approved for supportive care for patients with cancer. We look forward to making NYVEPRIA available to U.S. patients and physicians later this year."

The FDA approval was based on the review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity of NYVEPRIA to its reference product.

"Chemotherapy-induced febrile neutropenia is a relatively common and severe side effect of some cancer treatments that could cause significant complications and can result in the alteration of treatment regimens," said Ali McBride, PharmD, MS, BCPS, BCOP, Immediate Past President of the Association of Community Cancer Centers (ACCC). "The FDA approval of NYVEPRIA provides clinicians with an additional long-acting treatment option that can help prevent infections in patients undergoing myelosuppressive chemotherapy."

Biosimilars play an important role in the treatment of cancer or as supportive care, with the ability to both help increase patient access to essential medicines and provide value to the healthcare system by driving market competition that can lower the cost of care. With more than a decade of global in-market experience, a portfolio of nine approved biosimilar products in the U.S. and the broadest biosimilar portfolio for oncology supportive care, Pfizer is proud to be a global leader in biosimilars and at the forefront of this vital healthcare segment. Pfizer has also filed its pegfilgrastim biosimilar candidate for regulatory approval with the European Medicines Agency (EMA) and the application is currently under review.

Pfizer is committed to ensuring that patients who are prescribed NYVEPRIA have access to this therapy. Upon launch, patients in the U.S. will have access to Pfizer Oncology Together™, which offers personalized support and financial assistance resources to help patients access their prescribed Pfizer Oncology medications. Pfizer Oncology Together can help patients understand their benefits and connect them with financial assistance resources, regardless of their insurance coverage.

About NYVEPRIA (pegfilgrastim-apgf)

NYVEPRIA, a biosimilar to Neulasta, is approved by the FDA to help reduce the chance of infection due to a low white blood cell count in people with non-myeloid cancer who receive anti-cancer medicines, like chemotherapy, that can cause fever and low white blood cell count.[2] This condition, known as febrile neutropenia, is a common side effect of many types of chemotherapy and lowers the body's ability to defend itself against infections.[3]

NYVEPRIA INDICATION AND IMPORTANT SAFETY INFORMATION

Indication

NYVEPRIA is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

Limitations of Use

NYVEPRIA is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Important Safety Information

Contraindication

- NYVEPRIA is contraindicated in patients with a history of serious allergic reactions to pegfilgrastim products or filgrastim products
- Reactions have included anaphylaxis

Splenic Rupture

- Splenic rupture, including fatal cases, can occur following the administration of pegfilgrastim products
- Evaluate for an enlarged spleen or splenic rupture in patients who report left upper abdominal or shoulder pain after receiving NYVEPRIA

Acute Respiratory Distress Syndrome (ARDS)

- Can occur in patients receiving pegfilgrastim products
- Evaluate patients who develop fever and lung infiltrates or respiratory distress after receiving NYVEPRIA
- Discontinue NYVEPRIA in patients with ARDS

Serious Allergic Reactions

- Serious allergic reactions, including anaphylaxis, can occur in patients receiving pegfilgrastim products
- 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 NYVEPRIA in patients with serious allergic reactions
- Do not administer NYVEPRIA to patients with history of serious allergic reactions to pegfilgrastim products or filgrastim products

Use in Patients with Sickle Cell Disorders

- Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disorders receiving pegfilgrastim products
- Discontinue NYVEPRIA if sickle cell crisis occurs

Glomerulonephritis

- Glomerulonephritis has occurred in patients receiving pegfilgrastim products
- The diagnoses were based on azotemia, hematuria (microscopic and macroscopic), proteinuria, and renal biopsy
- Generally, events of glomerulonephritis resolved after dose-reduction or discontinuation of pegfilgrastim products
- If suspected, evaluate for cause, and if causality is likely consider dose-reduction or interruption ofNYVEPRIA

Leukocytosis

- White blood cell counts of 100 x 10^9/L or higher have been observed in patients receiving pegfilgrastim products
- Monitoring of complete blood count (CBC) during NYVEPRIA therapy is recommended

Capillary Leak Syndrome (CLS)

- CLS has been reported after granulocyte-colony stimulating factor (G?CSF) administration, including pegfilgrastim products
- Characterized by hypotension, hypoalbuminemia, edema, and hemoconcentration
- Episodes vary in frequency and severity and may be life?threatening if treatment is delayed
- Patients with symptoms should be closely monitored and receive standard symptomatic treatment, which may include intensive care

Potential for Tumor Growth Stimulatory Effects on Malignant Cells

- G-CSF receptor, through which pegfilgrastim and filgrastim products act, has been found on tumor cell lines
- The possibility that pegfilgrastim products act as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which pegfilgrastim products are not approved, cannot be excluded

Aortitis

- Aortitis has been reported in patients receiving pegfilgrastim products. It may occur as early as the first week after start of therapy
- Manifestations may include generalized signs and symptoms, such as fever, abdominal pain, malaise, back pain, and increased inflammatory markers (e.g., c?reactive protein and white blood cell count)
- Consider aortitis in patients who develop these signs and symptoms without known etiology. Discontinue NYVEPRIA if aortitis is suspected

Nuclear Imaging

- Increased hematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone imaging changes. This should be considered when interpreting

bone imaging results

Most Common Adverse Reactions

- Bone pain
- Pain in extremity

Please see full Prescribing Information and Patient Information for NYVEPRIA.

About Pfizer Oncology

At Pfizer Oncology, we are committed to advancing medicines wherever we believe we can make a meaningful difference in the lives of people living with cancer. Today, we have an industry-leading portfolio of 23 approved innovative cancer medicines and biosimilars across more than 30 indications, including breast, genitourinary, colorectal, blood and lung cancers, as well as melanoma.

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE: The information contained in this release is as of June 11, 2020. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about NYVEPRIA (pegfilgrastim-apgf), including its potential benefits and anticipated U.S. launch timing, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the launch timing and commercial success of NYVEPRIA in the United States; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when applications for NYVEPRIA may be filed in any other jurisdictions; whether and when any such other applications for NYVEPRIA that may be pending including the application pending in Europe or filed may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether NYVEPRIA will be commercially successful; intellectual property and/or litigation implications; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or

commercial potential of NYVEPRIA; uncertainties regarding access challenges for our biosimilar products where our product may not receive appropriate formulary access or remains in a disadvantaged position relative to the innovator product; uncertainties regarding the impact of COVID-19 on our business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

[1] Neulasta is a registered trademark of Amgen, Inc.
[2] NYVEPRIA Prescribing Information. Pfizer Inc. New York, NY.
[3] Punnapuzha S, Edemobi PK, Elmoheen A. Febrile Neutropenia. [Updated 2019 Dec 30]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2020 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK541102/.

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