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# Pfizer Receives European Approval for Oncology Supportive Care Biosimilar, NYVEPRIATM (pegfilgrastim)

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New York, NY, November 20, 2020 – Pfizer Inc. (NYSE: PFE) today announced that the European Commission (EC) has approved NYVEPRIA™ (pegfilgrastim), a biosimilar to Neulasta® (pegfilgrastim), to reduce the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukemia and myelodysplastic syndromes).[1,2] Febrile neutropenia is a common side effect of cancer treatments such as chemotherapy, which can leave patients vulnerable to infections.[3]

“The development of febrile neutropenia in people living with cancer who are undergoing chemotherapy can be a very serious complication,” said Paul Cornes, MD, oncologist and member of the continuing medical education program of the European Association of Hospital Pharmacists and core lecturer for the European School of Oncology. “The EC approval of NYVEPRIA provides clinicians with an alternative long-acting option that can help prevent infections.”

The EC approval is based on a comprehensive data package and totality of evidence demonstrating a high degree of similarity of NYVEPRIA to its reference product.

With more than 10 years of global in-market experience and a portfolio of nine biosimilar products which have received regulatory approval, Pfizer is proud to be a global leader of this vital healthcare segment. NYVEPRIA is Pfizer’s sixth approved oncology biosimilar and third approved supportive care biosimilar in Europe.

“Today’s approval of NYVEPRIA reflects Pfizer’s commitment to biosimilar medicines, which can generate savings for healthcare systems and increase patient access to important treatment options,” said Masum Hossain, Regional President, Oncology, International Developed Markets at Pfizer. “We are excited by the promise that treatments like NYVEPRIA can offer to the European healthcare system by driving market competition that can help lower the cost of care.”

Pfizer intends to make NYVEPRIA available to patients in several European countries starting in Q1 2021.

European Marketing Authorization of NYVEPRIA follows the medicine’s approval by the U.S. Food and Drug Administration in June 2020. In the U.S., NYVEPRIA (pegfilgrastim-apgf) is approved 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. [4]

**About NYVEPRIA (pegfilgrastim biosimilar)**

NYVEPRIA, a biosimilar to Neulasta, is approved by the EMA to reduce the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukemia and myelodysplastic syndromes). [1] 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 safety information

Do not use NYVEPRIA if you are allergic to pegfilgrastim, filgrastim, or any of the other ingredients of this medicine.

Before starting treatment with NYVEPRIA, talk to your doctor, pharmacist or nurse if:

- you have recently had a serious lung infection (pneumonia), fluid in the lungs (pulmonary edema), inflammation of the lungs (interstitial lung disease), or an abnormal chest x ray (lung infiltration).
- you are aware of any altered blood cell counts (e.g. increase in white blood cells or anemia) or decreased blood platelet counts (thrombocytopenia), which reduces the ability of your blood to clot. Your doctor may want to monitor you more closely.
- you have sickle cell anemia. Your doctor may monitor your condition more.
- you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby.

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

Tell your doctor immediately if you develop any of the following side effects while taking NYVEPRIA:

- swelling or puffiness.
- passing urine less frequently.
- difficulty breathing.
- abdominal (belly) swelling and feeling of fullness.
- a general feeling of tiredness.

These symptoms generally develop quickly and could signify an uncommon condition called capillary leak syndrome, which causes blood to leak from small blood vessels into your body and requires urgent treatment.

While taking NYVEPRIA, talk to your doctor, pharmacist or nurse if:

- you get an allergic reaction including weakness, drop in blood pressure, difficulty breathing, swelling of the face, lips, tongue or other parts of the body (anaphylaxis), redness and flushing, skin rash or hives on the skin and areas of the skin that itch.
- you get a cough or fever, and have difficulty breathing. This can be a sign of acute respiratory distress syndrome (ARDS).
- you get left upper abdominal pain or pain at the tip of your shoulder. This may be a sign of a problem with your spleen (splenomegaly).
- you get fever, abdominal pain, malaise, and back pain as these may be symptoms of inflammation of the aorta (the large blood vessel which transports blood from the heart to the body). This disorder can occur rarely in cancer patients and healthy donors.
- you become pregnant.

Other very common side effects of NYVEPRIA treatment include:

- bone pain or general aches and pains in the joints and muscles.
- feeling sick (nausea) and headaches.
- pain at the site of injection.
- chest pain not related to heart disorders.
- some changes may occur in your blood, but these will be detected by routine blood tests. Your white blood cell count may become high for a short period. Your platelet count may become low which might result in bruising.

**Skin reactions**

Severe skin reactions (Stevens-Johnson syndrome; a skin condition that causes painful blisters and sores of the skin and mucous membranes, especially in the mouth) have been reported with the use of pegfilgrastim. Stop using NYVEPRIA and get medical attention immediately if you notice any of these symptoms: reddish target like or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes possibly with fever and flu-like symptoms beforehand.

**Blood cancer**

You should talk to your doctor about your risks of developing cancers of the blood. If you have a cancer of the blood or have been told by your doctor that you are at risk of one, you should not use NYVEPRIA, unless instructed by your doctor.

Like all medicines, NYVEPRIA can cause side effects, although not everybody gets them. Most side effects are mild to moderate, but some may be serious and require treatment. Your doctor will check your blood and urine regularly as NYVEPRIA can damage your kidneys (glomerulonephritis).

Please refer to the European Summary of Product Characteristics for NYVEPRIA for complete safety information.

**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 November 20, 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), including its potential benefits and anticipated 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; 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 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 Pfizer. Data on File. European Commission Approval Letter 2020. 2 Neulasta® is a registered trademark of Amgen, Inc. 3 Marshall & Innes. (2008). Chemotherapy induced febrile neutropenia: management and prevention. Clinical medicine (London, England), 8(4), 448– 451. 4 NYVEPRIA Prescribing Information. Pfizer Inc. New York, NY For immediate release: Media Contact: Steve Danehy M: +1 212-733-1538 E: Steven.Danehy@pfizer.com Lisa O'Neill M: +44 7929 339 560 E: Lisa.O'Neill@pfizer.com Investor Contact:  Bryan Dunn M: +1 212-733-8917 E: Bryan.Dunn@pfizer.com