Nypozi™ (filgrastim-txid) – New biosimilar approval

- On June 28, 2024, the FDA approved Tanvex's Nypozi (filgrastim-txid), biosimilar to Amgen's Neupogen (filgrastim).
    - Nypozi is the fourth FDA-approved biosimilar to Neupogen. Zarxio® (filgrastim-sndz), Nivestym® (filgrastim-aafi) and Releuko® (filgrastim-ayow) have all previously launched.
- Nypozi, Zarxio, Nivestym, Releuko and Neupogen share the following indications:
    - Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
    - Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML)
    - Reduce the duration of neutropenia and neutropenia-related clinical sequelae, eg, febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT)
    - Reduce the incidence and duration of sequelae of severe neutropenia (eg, fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.
- Nypozi, Zarxio, Nivestym and Neupogen also share the following indication:
    - Mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.
- Nypozi and Neupogen also share the following indication:
    - Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome).
- The approval of Nypozi is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Neupogen.
- Warnings and precautions for Nypozi are splenic rupture, acute respiratory distress syndrome, serious allergic reactions, sickle cell disorders, glomerulonephritis, alveolar hemorrhage and hemoptysis, capillary leak syndrome, myelodysplastic syndrome and AML, thrombocytopenia, leukocytosis, cutaneous vasculitis, potential effect on malignant cells, simultaneous use with chemotherapy and radiation therapy not recommended, nuclear imaging, and aortitis.
- The most common adverse reactions (≥ 5% difference compared to placebo) with Nypozi use in nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs were pyrexia, pain, rash, cough, and dyspnea.
- The most common adverse reactions (≥ 2% difference) with Nypozi use in AML were pain, epistaxis and rash.
- The most common adverse reaction (≥ 5% difference) with Nypozi use in BMT was rash.

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- The most common adverse reactions (≥ 5% difference) with Nypozi use in peripheral blood progenitor cell mobilization and collection were bone pain, pyrexia and headache.
- The most common adverse reactions (≥ 5% difference) with Nypozi use in severe chronic neutropenia were pain, anemia, epistaxis, diarrhea, hypoesthesia and alopecia.
- The recommended dosage of Nypozi is given as a mg/kg intravenous infusion or subcutaneous injection.
    - Refer to Nypozi's drug label for further administration and dosing recommendations.
- Tanvex's launch plans for Nypozi are pending. Nypozi will be available as 300 mcg/0.5 mL and 480 mcg/0.8 mL prefilled syringes with BD UltraSafe Passive™ Needle Guard.

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