

Ryzneuta[®] (efbemalenograstim alfa-vuxw) – New drug approval

- On November 16, 2023, the [FDA approved](#) Evive Biotechnology's [Ryzneuta \(efbemalenograstim alfa-vuxw\)](#), to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
 - Ryzneuta is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.
- Ryzneuta is a long-acting granulocyte colony-stimulating factor (G-CSF).
- The efficacy of Ryzneuta was established in two randomized, controlled studies.
- Study GC-627-04 was a randomized, double-blind, placebo-controlled study that employed doxorubicin 60 mg/m² and docetaxel 75 mg/m² administered every 21 days for up to 4 cycles for the treatment of metastatic or nonmetastatic breast cancer. In this study, 122 patients were randomized to receive a single dose of Ryzneuta or placebo on day 2 of chemotherapy cycle 1. All patients received Ryzneuta on day 2 of chemotherapy cycles 2 – 4.
 - Efficacy was based upon the mean duration of severe (Grade 4) neutropenia in cycle 1 which was lower for Ryzneuta-treated patients as compared to placebo-treated patients (least squares mean: 1.4 days vs. 4.3 days, respectively, $p < 0.001$ [95% CI: 2.4, 3.5]).
 - The incidence of febrile neutropenia was also lower for Ryzneuta-treated patients compared to placebo-treated patients in cycle 1 (4.8% vs. 25.6%, respectively, $p = 0.0016$; 20.8% difference [95% CI: 1.8, 38.8]).
- Study GC-627-05 was a randomized, active-controlled study that compared Ryzneuta to pegfilgrastim. Study GC-627-05 employed docetaxel 75 mg/m² and cyclophosphamide 600 mg/m² administered every 21 days for up to 4 cycles for the treatment of non-metastatic breast cancer. In this study, 393 patients were randomized to receive a single dose of Ryzneuta or pegfilgrastim on day 2 of each chemotherapy cycle.
 - The study demonstrated that the mean days of severe (Grade 4) neutropenia of Ryzneuta-treated patients did not exceed that of pegfilgrastim-treated patients by more than 0.6 days in cycle 1 of chemotherapy.
 - The mean days of severe neutropenia in cycle 1 were 0.2 days in both the Ryzneuta and pegfilgrastim arms (difference in means 0.0 days [95% CI: -0.1, 0.1]).
- Warnings and precautions for Ryzneuta include splenic rupture; acute respiratory distress syndrome; serious allergic reactions; sickle cell crisis in patients with sickle cell disorders; glomerulonephritis; leukocytosis; thrombocytopenia; capillary leak syndrome; potential for tumor growth stimulatory effects on malignant cells; myelodysplastic syndrome and acute myeloid leukemia in patients with breast and lung cancer; aortitis; and nuclear imaging.
- The most common adverse reactions ($\geq 10\%$) with Ryzneuta use were nausea, anemia, and thrombocytopenia.
- The recommended dose of Ryzneuta is a single subcutaneous injection of 20 mg administered once per chemotherapy cycle at least 24 hours after cytotoxic chemotherapy. Ryzneuta should not be administered within 14 days before and < 24 hours after administration of cytotoxic chemotherapy.

- Ryzneuta should be administered by a healthcare professional.
- Evive Biotechnology's launch plans for Ryzneuta are pending. Ryzneuta will be available as a 20 mg/mL solution in a single-dose prefilled syringe.



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