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Evive Biotech & Aurobindo Pharma's cancer treatment receives US FDA approval

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US FDA approves Ryzneuta™: A breakthrough in cancer treatment

In a groundbreaking development, Evive Biotech and Acrotech Biopharma have announced that the US Food and Drug Administration (FDA) has granted approval for Ryzneuta™ (Efbemalenograstim alfa).

Developed by Evive Biotech, a global biopharmaceutical company, and a subsidiary of Yifan Pharmaceutical Co., in collaboration with Acrotech Biopharma, a New Jersey-based subsidiary of Aurobindo Pharma USA Inc., Ryzneuta™ is a novel biologic therapy indicated to decrease the incidence of infection in adult patients with non-myeloid malignancies undergoing myelosuppressive anti-cancer drugs.

The approval, granted on November 16, 2023, is based on the successful completion of two pivotal Phase 3 studies, GC-627-04 and GC-627-05, conducted in the United States and Europe.

Ryzneuta™, a long-acting Granulocyte colony-stimulating factor (G-CSF), stimulates the proliferation, differentiation, and release of neutrophil precursors, thereby enhancing the immune function of cancer patients and preventing neutropenia-related side effects caused by chemotherapy.

Study GC-627-05, a multi-center, randomized, multi-dose, active-controlled study comparing Ryzneuta™ with Neulasta™ (Pegfilgrastim), met its primary and secondary endpoints of efficacy and safety. Neutropenia, a common side effect of chemotherapy, increases the risk of adverse reactions in cancer patients.