Lupin gets FDA nod for white blood cell booster Neulasta Biosimilar

Armlupeg, a biosimilar of Amgen's Neulasta is a white blood cell booster is indicated to Increase survival in patients acutely exposed to myelosuppressive doses of radiation

Mumbai: Lupin Limited has secured US FDA approval for Neulasta (Pegfilgrastim-unne) biosimilar Armlupeg.

Armlupeg, a biosimilar of Amgen's Neulasta is a white blood cell booster is indicated to Increase survival in patients acutely exposed to myelosuppressive doses of radiation

The drug also helps to decrease the incidence of infection, in patients receiving myelosuppressive anti-cancer drugs.

As of September this year, the U.S. market for pegfilgrastim is estimated to exceed $1.2 billion. However, with the entry of biosimilar alternatives, the segment has seen a sharp decline in value. The innovator brand—Neulasta—reported a 49 per cent drop in sales, falling to $431 million in 2024.

"We are proud to achieve the FDA approval for our first biosimilar, Pegfilgrastim. This step marks a pivotal step in Lupin's ongoing commitment to providing more affordable, accessible medicines to U.S. patients.

The approval from U.S. regulators adds momentum to Lupin's long-term biosimilars strategy, under which the company is looking to to launch as many as five therapies over the next five years, through 2030.

"We look forward to introducing a robust portfolio of biosimilars over the next few years, which will help improve the quality of care for the communities and patients we serve," said Vinita Gupta, CEO, Lupin.

"Our integrated biologic capabilities encompass the entire spectrum, from initial cell line development to upstream/downstream process optimization and clinical development.," Nilesh Gupta, MD, Lupin, added.

News Source:

https://pharma.economictimes.indiatimes.com/news/drug-approvals-and-launches/lupin-gets-fda-nod-for-white-blood-cell-booster-neulasta-biosimilar/125694277