Lupin and Natco receive US FDA approval for breast cancer drug eribulin mesylate injection

Pharma major Lupin Limited and its alliance partner Natco Pharma Limited announced the approval from the United States Food and Drug Administration (FDA) for the latter's Abbreviated New Drug Application (ANDA) for eribulin mesylate injection, 1 mg/2 mL (0.5 mg/mL) single-dose vials.

Eribulin mesylate injection, 1 mg/2 mL (0.5 mg/mL) single-dose vials is bioequivalent to the reference listed drug (RLD) Halaven injection of Eisai, Inc.

Eribulin mesylate injection is indicated for the treatment of adults with metastatic breast cancer who have previously received at least two chemotherapeutic regimens for the treatment of metastatic disease, and unresectable or metastatic liposarcoma who have received a prior anthracycline-containing regimen.

Eribulin mesylate Injection (RLD Halaven) had estimated annual sales of $ 43.7 million in the US according to the IQVIA report on Moving Annual Total for April 2026.

Mumbai-based Lupin Limited enjoys a strong position in India and the US across multiple therapy areas, including respiratory, cardiovascular, anti-diabetic, anti-infective, gastrointestinal, central nervous system, and women's health.

Lupin has 15 state-of-the-art manufacturing sites and 7 research centers globally, along with a dedicated workforce of over 24,000 professionals. Lupin is committed to improving patient health outcomes through its subsidiaries – Lupin Diagnostics, Lupin Digital Health, and Lupin Manufacturing Solutions.

Hyderabad-based Natco Pharma develops, manufactures and distributes generic and branded pharmaceuticals, specialty pharmaceuticals, active pharmaceutical ingredients and crop protection products. The company has 9 manufacturing sites and 2 R&D facilities in India.

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