

Lupin receives FDA approval for Azacitidine for Injection, 100 mg Single-Dose Vial

Mumbai, Baltimore, February 28, 2019: Pharma major Lupin announced that it has received approval for its Azacitidine for Injection, 100 mg Single-Dose Vial from the United States Food and Drug Administration (FDA) to market a generic version of Celgene Corporation's Vidaza®. With this approval, Lupin strengthens its complex generics portfolio in Injectables.

Lupin's Azacitidine for Injection, 100 mg Single-Dose Vial is a generic version of Celgene Corporation's Vidaza®. It is indicated for treatment of patients with the following French-American-British (FAB) myelodysplastic syndrome subtypes: refractory anemia (RA) or refractory anemia with ringed sideroblasts (if accompanied by neutropenia or thrombocytopenia or requiring transfusions), refractory anemia with excess blasts (RAEB), refractory anemia with excess blasts in transformation (RAEB-T), and chronic myelomonocytic leukemia (CMML).

Azacitidine for Injection, 100 mg Single-Dose Vial had annual sales of approximately USD 112 million in the US (IQVIA MAT December 2018).

Lupin's state-of-the-art Mihan facility at Nagpur commissioned recently has the production capabilities for injectables with vials, lyophilised vials and Pre-filled Syringes (PFS). It received an EIR from US FDA in December 2018.

About Lupin Limited

Lupin is an innovation led transnational pharmaceutical company developing and delivering a wide range of branded & generic formulations, biotechnology products and APIs globally. The Company is a significant player in the Cardiovascular, Diabetology, Asthma, Pediatric, CNS, GI, Anti-Infective and NSAID space and holds global leadership position in the Anti-TB segment.

Lupin is the 8th largest generics pharmaceutical company in terms of market capitalization (28th December 2018, Bloomberg) and the 8th largest generics pharmaceutical company in terms of revenues (30th September 2018, Bloomberg LTM) globally. The Company is the 3rd largest pharmaceutical player in the US by prescriptions for the Total Market (IQVIA MAT December 2018); 3rd largest Indian pharmaceutical company by global revenues (30th September 2018, Bloomberg LTM); 6th largest generic pharmaceutical player in Japan (IQVIA MAT December 2018) and 5th largest company in the Indian Pharmaceutical Market (IQVIA MAT December 2018).

For the financial year ended 31st March, 2018, Lupin's Consolidated sales and Net profits before exceptional items were at Rs. 155,598 million (USD 2.41 billion) and Rs. 13,934 million (USD 216 million) respectively. Please visit <http://www.lupin.com> for more information. You could also follow us on Twitter – [www.twitter.com/lupinglobal](https://twitter.com/lupinglobal)

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Press Release



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**Safe Harbor Statement*

Vidaza® is a registered trademark of Celgene Corporation