

Zydu Cadila receives its first complex injectable approval from USFDA for Doxorubicin Hydrochloride Liposome Injection

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Zydu Cadila has received final approval from the USFDA to market Doxorubicin Hydrochloride Liposome Injection (US RLD: Doxil Liposome Injection) in the strengths of 20 mg/10 mL (2 mg/mL) and 50 mg/25 mL (2 mg/mL) Single-Dose Vials. This is the group's first approval for a complex injectable which has been developed in-house and will be manufactured at group's facility located in SEZ. The Company's injectable portfolio has 39 products under development with an addressable market size of \$20bn. U.S. sales for Liposomal Doxorubicin Injection were approximately \$124 million for the 12 months ending July 2020, according to IQVIA.

Speaking on the development, Managing Director, Dr. Sharvil Patel said, "This FDA approval of Liposomal Doxorubicin Injection demonstrates our long-term commitment to drive growth through investment in complex generic products. The approval further builds on Zydu's proven track-record of successfully commercializing and gaining meaningful market share in complex generics products, we expect our long term investment reap dividends, as we create an industry leading portfolio of complex products. Through this investment, we have created a diversified portfolio of complex ANDAs. This portfolio provides continued opportunities to grow our US business in 2021 and beyond." Through its long-term investments & focus on innovation, Zydu has created an industry leading portfolio of complex injectable products, drug device combination products, topicals, transdermal patches, difficult-to-develop solid oral products and first-to-file products.

Liposomal doxorubicin is a chemotherapeutic agent that is used alone or with other treatments/medications to treat certain types of cancer such as ovarian cancer, AIDS-related Kaposi's sarcoma and multiple myeloma. It works by slowing or stopping cancer cell growth.

The group now has 300 approvals and has so far filed over 390 ANDAs since the commencement of the filing process in FY 2003-04.

About Zydu Cadila

Zydu Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare therapies. The group employs nearly 25000 people worldwide and is dedicated to creating healthier communities globally.
