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## Dr. Reddy's Laboratories announces the launch of Deferasirox Film-Coated Tablets, in the U.S. Market

Hyderabad, India, December 6, 2019

For Immediate Release

Hyderabad, India and Princeton, NJ, USA. December 6, 2019 — Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, along with its subsidiaries together referred to as "Dr. Reddy's") today announced the launch of Deferasirox Film-Coated Tablets, 90 mg and 360 mg, a therapeutically equivalent generic version of Jadenu® (deferasirox) Film-Coated Tablets, 90 mg, 180 mg, and 360 mg, approved by the U.S. Food and Drug Administration (USFDA).

The Jadenu® brand had U.S. sales of approximately \$470 million MAT for the most recent twelve months ending in September 2019 according to IQVIA Health\*.

Dr. Reddy's Deferasirox Film-Coated Tablets, are available in 90 mg and 360 mg dosage strengths in bottle count sizes of 30.

### **WARNING: RENAL FAILURE, HEPATIC FAILURE, AND GASTROINTESTINAL HEMORRHAGE**

#### **Renal Failure**

- Deferasirox can cause acute renal failure and death, particularly in patients with comorbidities and those who are in the advanced stages of their hematologic disorders.
- Evaluate baseline renal function prior to starting or increasing deferasirox dosing in all patients. Deferasirox is contraindicated in adult and pediatric patients with eGFR less than 40 mL/min/1.73 m<sup>2</sup>. Measure serum creatinine in duplicate prior to initiation of therapy. Monitor renal function at least monthly. For patients with baseline renal impairment or increased risk of acute renal failure, monitor renal function weekly for the first month, then at least monthly. Reduce the starting dose in patients with preexisting renal disease. During therapy, increase the frequency of monitoring and modify the dose for patients with an increased risk of renal impairment, including use of concomitant nephrotoxic drugs, and pediatric patients with volume depletion or overchelation [see Dosage and Administration (2.1, 2.4, 2.5), Warnings and Precautions (5.1), Adverse Reactions (6.1, 6.2)].

#### **Hepatic Failure**

- Deferasirox can cause hepatic injury including hepatic failure and death.
- Measure serum transaminases and bilirubin in all patients prior to initiating treatment, every 2 weeks during the first month, and at least monthly thereafter.
- Avoid use of deferasirox in patients with severe (Child-Pugh C) hepatic impairment and reduce the dose in patients with moderate (Child-Pugh B) hepatic impairment [see Dosage and Administration (2.4), Warnings and Precautions (5.2)].

#### **Gastrointestinal Hemorrhage**

- Deferasirox can cause gastrointestinal (GI) hemorrhages, which may be fatal, especially in elderly patients who have advanced hematologic malignancies and/or low platelet counts.
- Monitor patients and discontinue deferasirox for suspected GI ulceration or hemorrhage [see Warnings and Precautions (5.3)].

Please refer to the Package Insert for the full prescribing information including boxed warning.

Jadenu® is a trademark of Novartis AG.

\*IQVIA Retail and Non-Retail MAT September 2019.  
RDY-0719-259

**About Dr. Reddy's:** Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY) is an integrated pharmaceutical company, committed to providing affordable and innovative medicines for healthier lives. Through its three businesses - Pharmaceutical Services & Active

Ingredients, Global Generics and Proprietary Products – Dr. Reddy's offers a portfolio of products and services including APIs, custom pharmaceutical services, generics, biosimilars and differentiated formulations. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Dr. Reddy's operates in markets across the globe. Our major markets include – USA, India, Russia & CIS countries, and Europe. For more information, log on to: [www.drreddys.com](http://www.drreddys.com)

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The company assumes no obligation to update any information contained herein.