

## DR. REDDY'S LABORATORIES LTD.

8-2-337, Road No. 3, Banjara Hills,  
Hyderabad - 500034. Telangana, India.

### CONTACT

#### INVESTOR RELATIONS

AMIT AGARWAL  
[amita@drreddys.com](mailto:amita@drreddys.com)  
(PH: +91-40-49002135)

#### MEDIA RELATIONS

MITALI SARKAR  
[mitali.sarkar@drreddys.com](mailto:mitali.sarkar@drreddys.com)  
(PH: +91-40- 49002121)

## Dr. Reddy's Laboratories announces the launch of Deferasirox Tablets for Oral Suspension, 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 Tablets for Oral Suspension, a therapeutically equivalent generic version of Exjade® (deferasirox) Tablets for Oral Suspension, approved by the U.S. Food and Drug Administration (USFDA).

The Exjade® brand had U.S. sales of approximately \$113 million MAT for the most recent twelve months ending in September 2019 according to IQVIA Health\*.

Dr. Reddy's Deferasirox Tablets for Oral Suspension, are available in 125 mg, 250 mg, and 500 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.

Exjade® is a trademark of Novartis Pharma AG.

\*IQVIA Retail and Non-Retail MAT September 2019.  
RDY-0819-261

**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)

---

**Disclaimer:** This press release may include statements of future expectations and other forward-looking statements that are based on the management's current views and assumptions and involve known or unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. In addition to statements which are forward-looking by reason of context, the words "may", "will", "should", "expects", "plans", "intends", "anticipates", "believes", "estimates", "predicts", "potential", or "continue" and similar expressions identify forward-looking statements. Actual results, performance or events may differ materially from those in such statements due to without limitation, (i) general economic conditions such as performance of financial markets, credit defaults, currency exchange rates, interest rates, persistency levels and frequency / severity of insured loss events (ii) mortality and morbidity levels and trends, (iii) changing levels of competition and general competitive factors, (iv) changes in laws and regulations and in the policies of central banks and/or governments, (v) the impact of acquisitions or reorganization, including related integration issues.

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