

CONTACT

**DR. REDDY'S LABORATORIES LTD.** 8-2-337, Road No. 3, Banjara Hills, Hyderabad - 500034. Telangana, India. MEDIA RELATIONS

APARNA TEKURI aparnatekuri@drreddys.com (PH: +91-40- 49002446)

## Dr. Reddy's Laboratories announces the launch of FXR<sup>™</sup> (obeticholic acid) in India

Hyderabad, India, May 18, 2020

For Immediate Release

Hyderabad, India, May 18, 2020 — Dr. Reddy's Laboratories Ltd., today announced the launch of FXR<sup>™</sup>, a therapeutic equivalent generic version of Ocaliva® (obeticholic acid) in India, indicated for the treatment of Primary Biliary Cholangitis (PBC), in combination with Ursodeoxycholic Acid (UDCA) or as monotherapy in adults.

Commenting on the launch, M V Ramana, Chief Executive Officer, Branded Markets (India and Emerging Markets), Dr. Reddy's Laboratories said, "We are excited to be the first generic company to market Obeticholic Acid in India. The launch of FXR<sup>™</sup>, the first-in-class Farnesoid X receptor agonist represents Dr. Reddy's expertise to accelerate access to affordable alternatives for complex products. FXR<sup>™</sup> will be an important addition to our Hepatology portfolio."

Dr. Reddy's FXR<sup>™</sup> is available in strengths of 5mg and 10mg tablets.

PBC, is a rare chronic autoimmune disease, characterised by destruction of small bile ducts in the liver. The only approved treatment for PBC in India as of today is UDCA, which was approved almost two decades ago. \*Though considered as a first line treatment for PBC, up to 40% of the patients do not respond to UDCA treatment, leaving many PBC patients with no approved treatment option. In 2016, Obeticholic acid received accelerated approval for the treatment of PBC as an 'orphan drug' in the U.S.

Ocaliva® is a trademark of Intercept Pharmaceuticals.

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 business es - 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

**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, and (vi) the susceptibility of our industry and the markets addressed by our, and our customers', products and services to economic downturns as a result of natural disasters, epidemics, pandemics or other widespread illness, including conavirus (or COVID-19), and (vii) other risks and "Forward-Looking Statements" sections of our Annual Report on Form 20-F for the year ended March 31, 2019. The company assumes no obligation to update any information contained herein."

\*Source: <u>A Khanna and David E Jones - Novel strategies and therapeutic options for the management of primary biliary cholangitis; Therap Adv Gastroenterol. 2017 Oct; 10(10): 791–803.</u>