Press Release



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Dr. Reddy's Laboratories announces its launch of Saxagliptin and Metformin Hydrochloride Extended-Release Tablets in the U.S.

Hyderabad India; August 10, 2023 - Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY, along with its subsidiaries together referred to as "Dr. Reddy's"), today announced its launch of Saxagliptin and Metformin Hydrochloride Extended-Release Tablets in the U.S. market, a therapeutic equivalent generic version of KOMBIGLYZE® XR (saxagliptin and metformin hydrochloride extended release) tablets, approved by U. S. Food and Drug Administration (USFDA).

Dr. Reddy's Saxagliptin and Metformin Hydrochloride Extended-Release Tablets are supplied in a strength of 2.5 mg/1000 mg in bottle count of 60 and strengths of 5 mg/500 mg and 5 mg/1000 mg each in bottle counts of 30.

Please including click here to see the full prescribing information, boxed warning: https://drreddys.com/pil/150092247-PIL-Saxaql-Met-HCL-ER-Tab-US V3 fn.pdf.

WARNING: LACTIC ACIDOSIS See full prescribing information for complete boxed warning.

- Post-marketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. Symptoms included malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Laboratory abnormalities included elevated blood lactate levels, anion gap acidosis, increased lactate/pyruvate ratio; and metformin plasma levels generally >5 mcg/mL. (5.1)
- Risk factors include renal impairment, concomitant use of certain drugs, age >65 years old, radiological studies with contrast, surgery and other procedures, hypoxic states, excessive alcohol intake, and hepatic impairment. Steps to reduce the risk of and manage metformin-associated lactic acidosis in these high-risk groups are provided in the Full Prescribing Information. (5.1)
- If lactic acidosis is suspected, discontinue saxagliptin and metformin hydrochloride extended-release tablets and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended. (5.1)

KOMBIGLYZE® is a registered trademark of the AstraZeneca group of companies.

RDY-0723-570

About Dr. Reddy's: Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY) is a global pharmaceutical company headquartered in Hyderabad, India. Established in 1984, we are committed to providing access to affordable and innovative medicines. Driven by our purpose of 'Good Health Can't Wait', we offer a portfolio of products and services including APIs, generics, branded generics, biosimilars and OTC. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Our major markets include - USA, India, Russia & CIS countries, China, Brazil and Europe. As a company with a history of deep science that has led to several industry firsts, we continue to plan ahead and invest in businesses of the future. As an early adopter of sustainability and ESG actions, we released our first Sustainability Report in 2004. Our current ESG goals aim to set the bar high in environmental stewardship; access and affordability for patients; diversity; and governance. 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 coronavirus (or COVID-19), and (vii) other risks and uncertainties identified in our public filings with the Securities and Exchange Commission, including those listed under the "Risk Factors" and "Forward-Looking Statements" sections of our Annual Report on Form 20-F for the year ended March 31, 2023. The company assumes no obligation to update any information contained herein.