## **Press Release**



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# Dr. Reddy's Laboratories received approval of XEGLYZE™ (abametapir) lotion, 0.74%, in the U.S.

Hyderabad, India, July 27, 2020

For Immediate Release

Hyderabad, India and Princeton, NJ, USA., July 27, 2020 - Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, along with its subsidiaries together referred to as "Dr. Reddy's") today announced approval of XEGLYZE (abametapir) lotion, 0.74%, a 505(b)(1) NDA by the U.S. Food and Drug Administration (USFDA). The approval triggers the contractual precommercialization milestone of \$20 million payable to Hatchtech Pty Ltd. XEGLYZE is indicated for the topical treatment of head lice infestation in patients 6 months of age and older. The company is working to commercialize this product through partners.

### INDICATION AND USAGE

XEGLYZE is indicated for the topical treatment of head lice infestation in patients 6 months of age and older.

XEGLYZE should be used in the context of an overall lice management program:

- Wash (with hot water) or dry-clean all recently worn clothing, hats, used bedding and towels.
- Wash personal care items such as combs, brushes, and hair clips in hot water.

Use a fine-tooth comb or special nit comb to remove dead lice and nits.

### **IMPORTANT SAFETY INFORMATION:**

XEGLYZE contains benzyl alcohol. Systemic exposure to benzyl alcohol has been associated with serious and fatal adverse reactions including "gasping syndrome" in neonates and low birth weight infants. The "gasping syndrome" is characterized by central nervous system depression, metabolic acidosis, and gasping respirations. The minimum amount of benzyl alcohol at which toxicity may occur is not known. Premature and low-birth weight infants may be more likely to develop toxicity [see Use in Specific Populations (8.4)].

The safety and effectiveness of XEGLYZE have not been established in pediatric patients below the age of 6 months. Use is not recommended in pediatric patients under 6 months of age because of the potential for increased systemic absorption.

In order to prevent accidental ingestion in pediatric patients, XEGLYZE should only be administered under direct supervision of an adult.

Ingestion of benzyl alcohol in large quantities may result in gastrointestinal (nausea, vomiting, diarrhea) and central nervous system (headache, ataxia, convulsions, coma) adverse reactions. Serious adverse reactions may include respiratory depression and death.

For 2 weeks after XEGLYZE application, avoid taking drugs that are substrates of CYP3A4, CYP2B6 or CYP1A2. Otherwise, avoid use of XEGLYZE. (7)

Most common adverse reactions (incidence of ≥ 1%) were erythema, rash, skin burning sensation, contact dermatitis, vomiting, eye irritation, pruritus, and hair color changes.(6.1)

These are not all the side effects associated with XEGLYZE.

Please see Patient Information, Instructions For Use, Medication Guide and Full Prescribing Information for XEGLYZE.

You are encouraged to report negative side effects of prescription drugs. To report SUSPECTED ADVERSE REACTIONS, contact Dr. Reddy's Laboratories. Inc., at 1-888-966-8766 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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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: <a href="https://www.drreddys.com">www.drreddys.com</a>

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, (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, 2020.

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