# Press Release

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## Dr. Reddy's Laboratories Receives USFDA Tentative Approval for Zenavod™ (doxycycline) Capsules, 40 mg for the Treatment of Rosacea in Adults

**Hyderabad, India, February 1, 2016** **For immediate release**

Hyderabad, India, & Princeton, NJ, USA. February 01, 2016, Dr. Reddy's Laboratories (BSE: 500124, NSE: DRREDDY, NYSE: RDY), announced today the U.S. Food and Drug Administration (US FDA) tentative approval for Zenavod™ (doxycycline) Capsules, 40 mg. Zenavod is a tetracycline-class drug indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients. Promius™ Pharma, LLC, the U.S. subsidiary of India's Dr. Reddy's Laboratories will be responsible for commercializing Zenavod in the U.S. market.

"This development confirms our ability and commitment to develop differentiated dermatology products leveraging the in-house capabilities of Promius Pharma, LLC and Dr. Reddy's," stated G V Prasad, CEO and Co-Chairman, Dr. Reddy's Laboratories. He continued, "We are pleased to receive a tentative FDA approval of Zenavod and will be working with external parties and the FDA to gain a full approval."

The approval of the New Drug Application (NDA) is tentative because the FDA has determined that the drug meets all of the required quality, safety, and efficacy standards for approval, but it is subject to an automatic stay of final approval for up to 30 months pending a patent infringement process under the Drug Price Competition and Patent Term Restoration Act ("Hatch Waxman").

"The tentative approval for Zenavod is another step toward providing an additional option for people with rosacea in the U.S., who need oral treatment," said Dr. Raghav Chari, Executive Vice President of Proprietary Products at Dr. Reddy's and President of Promius Pharma, "We are looking forward to the commercial launch and continuing to enhance our support of medical dermatologists and their patients."

**INDICATION**:
ZENAVOD is indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients.

**IMPORTANT SAFETY INFORMATION**
ZENAVOD Capsules do not lessen the facial redness caused by rosacea. Some of the most common adverse reactions of doxycycline (incidence >2% and more common than with placebo) are nasopharyngitis, sinusitis, fungal infection, influenza, diarrhea, upper abdominal pain, hypertension, lactate dehydrogenase increase, anxiety and pain. Pseudomembranous colitis can occur with doxycycline therapy as can intracranial hypertension, and autoimmune syndromes. ZENAVOD Capsules should not be used to treat or prevent infections. ZENAVOD Capsules should not be taken by patients who have a known hypersensitivity to doxycycline or other tetracyclines. ZENAVOD Capsules should not be taken during pregnancy, by nursing mothers, or during tooth development (up to the age of 8 years). Photosensitivity can occur with doxycycline; patients should minimize or avoid exposure to natural or artificial sunlight. The efficacy of ZENAVOD Capsules treatment beyond 16 weeks and safety beyond 9 months have not been established.

**About Dr. Reddy's**: Dr. Reddy's Laboratories Ltd. (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 gastro-intestinal, cardiovascular, diabetology, oncology, pain management and anti-infectives. Dr. Reddy's operates in markets across the globe. Our major markets include – USA, Russia & CIS, Venezuela and India. For more information, log on to: www.drreddys.com

**About Promius Pharma**: Promius Pharma is a wholly owned subsidiary of Dr. Reddy's Laboratories, one of largest and most respected pharmaceutical companies in the world. Our approach to product development relies heavily on converting deep insights gained from patients and physicians combined with strong collaborations with KOLs throughout the development continuum into highly innovative product concepts. Current R&D pipeline and commercialized products address the needs of patients with dermatological and neurological conditions. The company has successfully established a robust commercial infrastructure and leverages the extensive research and development capabilities available through its parent company. For more information, log on to www.promiuspharma.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.