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Dr Reddy's receives tentative FDA approval for Zenavod

02 February 2016 | News | By BioSpectrum Bureau

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Dr Reddy's Laboratories has announced that the US 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, the US subsidiary of Dr Reddy's will be responsible for commercializing Zenavod in the US market.

"This development confirms our ability and commitment to develop differentiated dermatology products leveraging the in-house capabilities of Promius Pharma and Dr Reddy's," stated Mr G V Prasad, CEO and co-chairman, Dr Reddy's. 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 US, 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."