

Dr. Reddy's Laboratories Ltd. 8-2-337, Road No. 3, Banjara Hills, Hyderabad - 500 034, Telangana, India.

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Corporate Relationship Department BSE Limited Dalal Street, Fort <u>Mumbai – 400 001</u> Fax Nos.: 022-22723121 / 22723719 / 22722037 / 22722039 National Stock Exchange of India Ltd. "Exchange Plaza" Bandra-Kurla Complex, Bandra (East), Mumbai – 400 051 Fax Nos.: 022-26598120/ 26598237/ 26598238

Scrip Code: 500124

Scrip Code: DRREDDY-EQ

Dear Sirs,

Sub: Press Release

Please find enclosed a Press Release on "Dr. Reddy's Laboratories announces the re-launch of its Buprenorphine and Naloxone Sublingual Film after favorable ruling in patent litigation"

This is for your information and record.

With regards,

Vipralealelearcural_

Vikas Sabharwal Assistant Company Secretary

Encl: As above

CC:- New York Stock Exchange Inc.(Stock Code :RDY)

Press Release



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Dr. Reddy's Laboratories announces the re-launch of its **Buprenorphine and Naloxone Sublingual Film** after favorable ruling in patent litigation

Hyderabad, India, February 20, 2019

For Immediate Release

Hyderabad, India and Princeton, NJ, USA. February 20, 2019 - Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, along with its subsidiaries together referred to as "Dr. Reddy's") announced today the re-launch of its Buprenorphine and Naloxone Sublingual Film, 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg, a therapeutic equivalent generic version of Suboxone® (buprenorphine and naloxone) sublingual film, in the United States market.

The re-launch comes on the heels of a favorable decision issued by the United States Court of Appeals for the Federal Circuit concluding that Indivior had not shown that it is likely to succeed on its claim that Dr. Reddy's product infringes U.S. Patent No. 9,931,305. The Federal Circuit's decision vacates the District Court's preliminary injunction that had prohibited Dr. Reddy's from selling its generic version of Suboxone® (buprenorphine and naloxone) sublingual film. The Federal Circuit's decision went into effective yesterday. As a result of the Federal Circuit's ruling, Dr. Reddy's has resumed shipping of the product.

"We are pleased with the decision of the appellate court in Dr. Reddy's favor, vacating the preliminary injunction that had prevented Dr. Reddy's from continuing to market this important drug to the public," explains Marc Kikuchi, Chief Executive Officer, North America Generics. "Dr. Reddy's is committed to providing affordable treatment options for opioid use disorder and addiction. We look forward to helping patients and our communities in the United States who are impacted by the opioid epidemic."

In June 2018, the U.S. Food and Drug Administration (USFDA) approved Dr. Reddy's Buprenorphine and Naloxone Sublingual Film, in four strengths including 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg, for sale in the U.S. market. The product was launched immediately after approval, with sales and commercialization activities halted as a result of a court-imposed temporary restraining order (TRO) and preliminary injunction against Dr. Reddy's. The TRO and preliminary injunction did not prohibit commercial manufacturing of the product.

Please click below for full Prescribing Information including Medication Guide.

http://www.drreddys.com/pi/Buprenorphine and Naloxone Sublingual Film 2mg-0.5mg and 8mg-2mg Prescribing Information.pdf

http://www.drreddys.com/pi/Buprenorphine and Naloxone Sublingual Film 4mg-1mg and 12mg-3mg Prescribing Information.pdf

Suboxone® is a registered trademark of Indivior UK Ltd.



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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: <u>www.drreddys.com</u>

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

