

# MOREPEN

Date: 20/12/2017

To,

**National Stock Exchange of India Ltd.**  
Exchange Plaza, Bandra Kurla Complex,  
Bandra (East), Mumbai- 400 051  
Tel No: (022) 26598100 - 8114  
Fax No: (022) 26598120  
Symbol: MOREPENLAB

**BSE Limited**  
Floor 25, Phiroze Jeejeebhoy Towers,  
Dalal Street, Mumbai- 400 001  
Phones: 91-22-22721233/4  
Fax: 91-22-2272 3121  
Scrip Code: 500288

**Subject: Press Release**

Dear Sir,


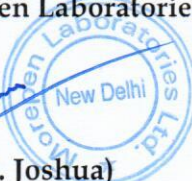
Please find enclosed the press release on 'Morepen gets US FDA clearance for its bulk drug Montelukast Sodium'.

Kindly acknowledge the receipt and take it on your record.

Thanking you.

Yours faithfully,

**For Morepen Laboratories Limited**

  
  
**(Thomas P. Joshua)**  
Company Secretary

Encl.: As Above

**Morepen Laboratories Limited**

**Corp. Off.:** 4th Floor, Antriksh Bhawan, 22 K.G.Marg, New Delhi- 110 001, INDIA  
Tel.: +91-11-23324443, 23712025, E-mail: corporate@morepen.com, Website: www.morepen.com  
CIN NO. L24231 HP1984PLC006028

**Plant & Regd. Off.:** Morepen Village, Malkumajra, Nalagarh Road, Baddi, Distt. Solan (H.P.) -173205  
Tel.: +91-1795-266401-03, 244590, Fax: +91-1795-244591, E-mail: plants@morepen.com





**MOREPEN**



## Press Release

# **Morepen gets US FDA clearance for its bulk drug Montelukast Sodium**

## ***The move propels Morepen's entry into Rs. 2000 crore US market for Montelukast Sodium***

**New Delhi, December 20, 2017:** The United States Food and Drug Administration (USFDA) has cleared Montelukast Sodium, a bulk drug / API manufactured by Morepen Laboratories Ltd, for sale in the US market. This gives Morepen an entry into the Rs. 2000 crore (Approx. \$ 300 million) US market for Montelukast. The first commercial orders for the bulk drug are expected in Q2 of FY 2018-19.

Expressing happiness on the development, **Mr. Sushil Suri, Chairman and Managing Director, Morepen Laboratories Ltd.**, said, "It's a big development for us as it is in recognition of our continuous efforts to produce world class API's over more than three decades. Our image as a quality API supplier gets cemented with the entry of Montelukast in the US market. It would provide a major boost to the company's top line and thus the bottom line in the years to come."

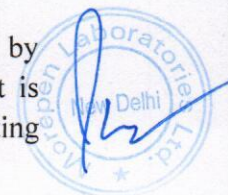
Montelukast's global market is estimated at about Rs 13000 crore (Approx. US\$ 2 billion) out of which US market alone is Rs. 2,000 crore. The patent for Montelukast has expired in all the markets worldwide. In U.S., the product patent got expired in 2012 and subsequently process patent expired in 2014.

Montelukast is another blockbuster product for Morepen after Loratadine. Morepen is amongst the largest producers of Montelukast globally with an annual capacity of more than 30 tons. Besides, Morepen is the market leader for Montelukast in India with over 50 per cent market share, supplying to almost all major finished dosage manufacturers in India. Already crossed Rs. 100 crore annual sales from Montelukast Sodium alone, Morepen is going to get a business of around Rs. 500 crore from this API in next 3-4 years.

Morepen holds process patent for Montelukast Sodium Amorphous for US, Canada and Europe markets. The company's manufacturing process yields very less impurities, very less residual solvents, higher assay, better colour of the API and is an environment friendly process as it does not involve use of class II solvents.

Morepen's API Montelukast supplies are regular to various countries in Europe and also to China. Morepen also holds accreditations for other countries including Canada, Russia, Taiwan, Iran for Montelukast. Commercial sales of Montelukast are presently reaching customers in about 35 countries. U.S. supplies would also commence following the USFDA clearance.

Montelukast is manufactured at Morepen's Masulkhana facility, which has been inspected by various global regulatory agencies like US FDA, EU GMP, TGA and others. Montelukast is manufactured under strict quality control complying with cGMP requirements and meeting





various other global manufacturing standards having already obtained COS (Certificate of Suitability) in Europe and IDL (Import Drug Licence) from China.

In the **First Half (H1) of FY 2017-18**, ended September 30, 2017, Morepen has reported a rise of 9 per cent in its net profit at Rs. 12.34 crore on its net sales of Rs. 257 crore. Morepen has also recently entered into a **tie-up with Vésale Pharma International of Belgium** to strengthen its position in the Rs. 1000 crore Probiotics market in India.

#### **About Morepen Laboratories Ltd.**

Morepen Laboratories Ltd. is a 33-year old, Rs. 600 Cr pharmaceutical and healthcare products company. The company went public in the year 1993 and is currently listed at both the Bombay Stock Exchange as well as the National Stock Exchange.

Morepen is engaged in the manufacturing and sale of APIs/ Bulk Drugs, Home Diagnostics, Formulations and OTC products. The company's state-of-the-art manufacturing facility at Baddi (Himachal Pradesh) comprises a scientifically integrated complex of 10 plants, each with a specific product profile. The USFDA approved plant at Masulkhana is for manufacture of Loratadine, an anti-allergy drug – internationally known as Claritin. The new blockbuster drug Montelukast is also manufactured at this FDA approved site.

The large and spread out manufacturing facility at Baddi manufactures latest and much in demand products like Atorvastatin, Rosuvastatin and others for regulated markets of USA and also for non-regulated markets across the globe.

Morepen markets over 100 branded formulations under six major therapeutic segments in the domestic market. It has WHO GMP facilities for manufacturing of Formulations. The company's manufacturing facilities are backed by a strong dedicated team of research and development (R&D) professionals who ensure stringent quality standards. In Home - Diagnostics business, Morepen has a formidable presence in Blood Glucose Monitors and Blood Pressure Monitors, in the domestic markets. The company's OTC brands are being promoted under its wholly owned subsidiary Dr. Morepen Limited. Dr. Morepen's famous OTC product line, including Burnol, Lemolate, Sat-Isabgol, Pain-X and others, has a significant presence in the domestic market.

The company's wholly owned subsidiary-Dr. Morepen Ltd. is setting up a first of its kind chain of healthcare centres in India by the name of Dr. Morepen NOW to offer ECP Therapy to target consumers in India. The move is part of the company's "Nation on Wellness (NOW)" drive, which envisions providing non-invasive means to treat cardiovascular diseases and diseases associated with cardio-metabolic issues gripping the country today. The first Dr. Morepen NOW clinic has been set up in Hauz Khas, New Delhi.

For Further Details, Please contact:

**Propel Communications,**

**Girish Singhal**

**Mb: 9810206244**

**Email: [propelpr.com@gmail.com](mailto:propelpr.com@gmail.com)**

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*The Joy of Growing Together*

