



MOREPEN



Date: 14/10/2019

To,

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Subject: Press Release - 'Morepen Labs adds three new drugs - Rivaroxaban, Vildagliptin and UDCA to its API portfolio.'

Dear Sir,


Please find enclosed the press release with the title - '**Morepen Labs adds three new drugs - Rivaroxaban, Vildagliptin and UDCA to its API portfolio.'**

Kindly acknowledge the receipt and take it on your record.

Thanking you.

Yours faithfully,

For Morepen Laboratories Limited


(Vipul Kumar Srivastava)
Company Secretary

Encl.: As Above

Morepen Laboratories Limited

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Press Release

Morepen Labs adds three new drugs - Rivaroxaban, Vildagliptin and UDCA to its API portfolio.

Highlights:

- Three new Drugs viz., **Rivaroxaban (Cardiac Segment)**, **Vildagliptin (Diabetes segment)** and **UDCA (for Liver ailments)** added to API portfolio.
- **Commercial launch** of all the three drugs announced by the company, supplies to commence soon.
- **Global market size** of Rivaroxaban is \$7.19 bn (Rs. 51,000 crore) and that of Vildagliptin is \$ 1.28 bn (Rs. 9,000 crore).
- **Rivaroxaban** is the 10th largest selling drug worldwide. Indian patent for the drug is expiring in December 2019.
- **Vildagliptin's** patent is expiring worldwide in December 2019. The drug enjoys 25 per cent share of the Indian Gliptins market valued at Rs. 3,500 crore.
- The three drugs will currently be sold in India and patent-free markets worldwide. DMF filing in the regulated markets likely within the next 12 months.
- **UDCA** is used for the treatment of Primary Biliary Cirrhosis, a liver disease which occurs due to improper functioning of liver. UDCA has a niche market of \$200million (Rs.1,400 cores). The drug is already patent-free worldwide.
- **Company recently got accreditation for its in- house R&D Centre at Baddi (HP) from Department of Scientific & Industrial Research, Govt. of India, New Delhi.** With this, the company has plans to invest in the areas of advance research related to new API molecules, patented technologies and new polymorphic form of the existing products

New Delhi, October 14, 2019: Morepen Laboratories Ltd. has developed and added three blockbuster drugs to its portfolio of Active Pharmaceutical Ingredients (APIs) for sale in domestic and global markets. The three bulk drugs / APIs are **Rivaroxaban (trade name- Xarelto)**, **Vildagliptin (trade names- Galvus, Zomelis)** and **UDCA (Ursodeoxycholic Acid)**. While two products Rivaroxaban and Vildagliptin will augment Morepen's presence in the Cardiac and Diabetic segments respectively, the third product UDCA will cater to the Liver segment.

The current global market size for **Rivaroxaban**, a powerful anticoagulant (blood thinner), is \$7.19Billion (Rs. 51,000 cores) and that of **Vildagliptin**, which is a strong oral Anti-diabetic drug used for the treatment of type 2 diabetes, is \$1.28 Billion (Rs. 9,000 cores). The global market size for Rivaroxaban is likely to touch \$9.00 Billion (Rs. 64,000 crore) by year 2023 and that of Vildagliptin \$1.35 Billion (Rs. 9,600 crore) by 2021. Morepen Labs will initially target patent free markets for these two drugs globally. The Drug Master File (DMF) for regulatory markets like US etc will be filed within the next 12 months' time frame.

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This was disclosed by **Mr. Sushil Suri, Chairman and Managing Director, Morepen Laboratories Ltd.**, here on Monday. “The company has already built-up additional capacities and is now all set to commercially launch these three new API’s under its portfolio. Dedicated efforts of Morepen’s in-house R&D Centre at Baddi (Himachal Pradesh), which was recently approved by Department of Scientific & Industrial Research, Govt. of India, has led to the release of these three products,” he said.

“With a focus on new molecules, new patented processes, we now look forward towards investing more in our R&D Infrastructure for future growth of the company,” Mr. Suri further pointed out.

Rivaroxaban is the 10th largest selling drug worldwide. It caters to the Cardiac market. It was initially developed and patented worldwide by Bayer. Morepen already has substantial presence in this category with two leading statins – Atorvastatin and Rosuvastatin that are aggressively being used for lowering cholesterol. Now with the addition of Rivaroxaban in Morepen’s portfolio, company gets an added advantage in the cardiac market. The Indian patent for the drug is going to expire in Dec’ 2019 which opens floodgates for the company to export the drug to all the patent free markets worldwide and also supply the product to the large domestic market where it is commonly used to prevent blood clots and used for cardiovascular symptoms such as angina, heart failure, rheumatic heart disease etc.

Vildagliptin caters to the Diabetics market worldwide. Morepen footprint in diabetic sector is well established with a series of “gliptins” like Sitagliptin, Linagliptin, Saxagliptin and new series of “gliflozins” like Empagliflozin and Dapagliflozin, already developed by Morepen’s R&D Centre. Development of low cost Vildagliptin, which is used for the treatment of metabolic disorders such as obesity, diabetes, PCOD & fatty liver etc., is a nice addition to growing Diabetic portfolio of the company. Vildagliptin patent is presently held by Novartis and this is set to expire worldwide in December 2019. Vildagliptin has about 25 per cent share of the Indian “gliptins” market of Rs. 3500 crore. Vildagliptin is the first molecule in the most commonly prescribed “gliptins” series that is going off patent and is certainly going to get good traction in the market.

UDCA is a niche product and has lot of technical challenges to synthesize. It is a naturally occurring product in the bile acid, found in normal human bile in small quantities. UDCA is used for the treatment of Primary Biliary Cirrhosis, a liver disease which occurs due to improper functioning of liver. It is also prescribed for the decrease in bile absorption, reduction in gallstone formation and also to relieve the symptoms of itching. UDCA has a niche market of \$200million (Rs. 1,400 cores) and is expected to touch \$300 million (Rs. 2,100 crore) by 2023. UDCA is already patent-free worldwide and ready for exporting across all the continents.

The **bulk drugs (API) segment** contributed marginally over 60 per cent to the company’s total turnover in Q1 FY 2019-20. API Exports grew by 50 percent during Q1 and domestic API business grew by 33 per cent in the quarter. Morepen Labs has plans to invest in the areas of advance research related to new API molecules, patented technologies and new

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polymorphic form of the existing products. This will also give a big boost to the fresh R&D initiatives of the company for investing in future.

About Morepen Laboratories Ltd. (www.morepen.com)

Morepen Laboratories Ltd. is a 35 year old, around Rs. 800 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. Desloratadine and the new blockbuster drug Montelukast is also manufactured at this FDA approved site. The large and spread out manufacturing facility at Baddi has EU GMP & WHO GMP Standards and manufactures latest and much in demand APIs like Atorvastatin, Rosuvastatin, Fexofenadine and others for regulated markets of Europe, 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. 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.

For Further Details, Please contact:

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