



MOREPEN



Date: 03/12/2021

To,

National Stock Exchange of India Ltd.
Exchange Plaza, Bandra Kurla Complex,
Bandra (East), Mumbai- 400 051
Symbol: MOREPENLAB

BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street, Mumbai- 400 001
Scrip Code: 500288

Subject: Press Release – ‘Morepen gets US FDA Approval for Fexofinadine (Allegra) Expected to start export in Q4’FY22’

Dear Sir/Ma’am,

Please find enclosed the press release with the title – ‘Morepen gets US FDA Approval for Fexofinadine (Allegra) Expected to start export in Q4’FY22’.

This is for your information and records.

Thanking you,

Yours faithfully,

For Morepen Laboratories Limited

Vipul Kumar Srivastava
Company Secretary



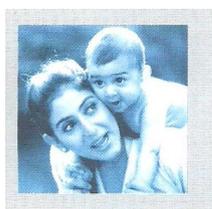
Encl.: as stated above.

Morepen Laboratories Limited

CIN No: L24231 HP1984PLC006028

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PRESS RELEASE

Morepen gets USFDA Approval for Fexofinadine (Allegra)

Expected to start export in Q4'FY22

New Delhi, December 3, 2021: Morepen Laboratories Limited (NSE: MOREPENLAB, BSE: 500288) has received USFDA approval for its anti-allergy drug Fexofinadine Hydrochloride that is market in India under the popular brand name Allegra, among others and is the block buster drug of the innovator company Sanofi Aventis, France. Fexofinadine is most widely used, second generation antihistamine drug for the treatment of allergy symptoms and hay fever.

The company has tied-up for regular supplies of Fexofinadine to one of its top US customers, with which the company has long standing relations lasting over two decades. The company has already supplied validation quantities and the regular commercial supplies would start after approval of validation batches. Fexofinadine is a very established anti-allergy drug with a market size of around 700MT and expected to give immediate impetus to company's export business.

Morepen is the third largest exporters of this drug to the world and will move up in the ranks after this approval. The export of Fexofenadine to the highly regulated US market is expected to see multi-fold growth resulting in better profitability margins for the company. The company is having sufficient capacity to service the present demand and is also expanding capacities to become a leading player in the product in the coming years.

Fexofinadine is among top five leading products of the company and is the fourth anti-allergy drug in the Morepen's product basket, in addition to Loratadine, Desloratadine and Montelukast. Morepen holds a leadership position in Loratadine group since last 20 years and was first to file for marketing permissions in USA markets. Fexofinadine is marketed primarily in two dosage forms 120mg and 180mg and is available to buy over the counter in many countries including USA, Australia, New Zealand, and certain countries around Europe. It is also used in combination with other anti-allergy drugs like Montelukast for which Morepen has got the largest manufacturing capacity in the world and is already approved in US market.

Mr. Sushil Suri, Chairman and Managing Director stated, "Approval of anti-allergy drug Fexofinadine (Allegra) by USFDA is an important milestone in the company's therapeutic journey since it consolidates Morepen's position in the anti-allergy market with already having USFDA approval for three lead products Loratadine, Desloratadine and Montelukast. It also cements our long-standing relations with our prime customers who have worked with us for two decades and shows their confidence in company's product quality and delivery"

This approval of Fexofenadine is the 5th product approved by USFDA at Morepen facilities based at Baddi, in the Solan district of State of Himachal Pradesh. The company has got an excellent track record with the USFDA regulators and have never got any major/critical observations during its inspections. Morepen has strong portfolio of APIs with market size of over US\$ 42 billion, which is going off patent over next 7-8 years and is building additional capacities in a multiphase USFDA expansion as demand for niche molecules and global customers remain stronger than ever and the market size, the company is looking to address, is US\$ 42 billion compared to US\$ 2 billion currently.

Morepen has been performing extremely well for last few years and had reported strong quarterly earnings with a stellar performance in Q2'FY22 with a growth of 70 per cent in its consolidated Profits (before tax) at Rs. 46.86 crores. Profit after tax (PAT) for the quarter has jumped 38 percent at Rs. 37.36 crores. The Quarterly revenues of the company at Rs. 398.17 crores have recorded an impressive growth of 17 percent during the current quarter as compared to quarterly revenues of Rs. 340.13 crores in Q2'FY21 where in it had registered a growth of 57 percent. This is sixth quarter in a row that the company continues the fast growth trajectory with remarkable gains in the bottom line.

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

Morepen Laboratories Ltd. is a 36-year-old, around Rs. 1200 Cr. pharmaceutical and healthcare products company. The company went public in the year 1992 and is currently listed at both the Bombay Stock Exchange (BSE) as well as the National Stock Exchange (NSE).

Morepen is a leading manufacturer of high-quality APIs, Home Diagnostics, Formulations and OTC products in north India. All the manufacturing facilities of the company are in the state of Himachal Pradesh and meet the latest international standards. Company's both API facilities at Masulkhana and Baddi are approved by USFDA and other regulatory bodies of Europe, Asia, and Australia. The company's state-of-the-art manufacturing facility at Baddi comprises a scientifically integrated complex of 10 plants, each with a specific product profile.

Amongst several APIs manufactured by Morepen, the company is the largest manufacturer of Loratadine and Montelukast (anti-allergy and anti-asthmatic drugs). It also enjoys a significant share for Atorvastatin and Rosuvastatin (Cholesterol reducing drugs) in the international market. Besides, the company has established an extensive footprint for its API products on the strength of quality, documentation and consistency in regulatory compliances, both in the domestic as well as global markets. Morepen has achieved to its credit the enduring confidence of a strong (over 1250) customer base spanning over 80 countries for its leading API products.

In line with its vision of keeping pace with the changing landscape, Morepen continues to invest in its Research and Development (R&D) infrastructure aimed at developing new molecules to deliver the latest drugs at competitive prices in the global markets. The company's strong dedicated R&D team has successfully developed 22 products in last three years out of which 12 products have already been commercialized. The company has also started supplying these new products to customers with complete documentation like DMF, tech packs and other regulatory compliances.

Morepen's R&D Centre meets all the global regulatory requirements and was recently approved by Department of Scientific & Industrial Research, Govt of India, New Delhi. Morepen R&D and QA team, known for its impeccable service, has filed 125 Patents, 60 DMFs and 8 CEPs for USA and Europe, Japan, China, Taiwan and Australian markets.

Morepen is also an established name in home diagnostics sector which remained untapped for a long time in India. Dr. Morepen has gained No.1 position in manufacturing and marketing of Blood Glucose Monitors in India, displacing some established multinational players. With a stable base of more than four million installations of Blood Glucose Monitors, the company has sold more than 785 million glucometer strips (single tests) till date. Dr. Morepen also has a formidable presence and is the leader in the Blood Pressure Monitors.

Brand Dr. Morepen (www.drmorepen.com), which was launched way back in 2001, has created a niche for itself in over the counter (OTC) and Self-Health segment products as well. Dr. Morepen has reached all over the country with over 50 products including famous brands like 'Burnol' and 'Lemolate'.

For more information on GUBB, please visit www.gubbworld.com

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