Marksans receives USFDA approval for Guaifenesin Extended-Release Tablets (OTC)

Mumbai, August 22, 2023 – Marksans Pharma Ltd. (NSE: MARKSANS; BSE:524404), one of the fastest-growing pharmaceutical companies in India, is pleased to announce that it has received final approval from the US Food and Drug Administration ("FDA") for its Abbreviated New Drug Application ("ANDA") for Guaifenesin Extended-Release Tablets, 600 mg and 1200 mg (OTC)

The Guaifenesin Extended-Release Tablets, 600 mg and 1200 mg (OTC) are bioequivalent to the reference listed drug (RLD), Mucinex Extended-Release Tablets, 600 mg and 1200 mg, of RB Health (US) LLC.

Guaifenesin extended-release tablets help to loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive. The company expects to launch the product immediately.

Commenting on the approval, Mark Saldanha, Managing Director of the Company said *"We are delighted to announce the approval, which further strengthens our growing Cough and Cold OTC portfolio in the US. We are confident in tapping the market opportunity of the product and remain committed to working diligently towards sustaining this momentum in the coming quarters."*

Disclaimer

Certain statements in this press release concerning our future growth prospects may be forward-looking statements, which involve several risks, and uncertainties that could cause actual results to differ materially from those in such forward-looking statements. The company's results may be affected by factors including, but not limited to, the risks and uncertainties in pharmaceutical research and development; competitive developments; regulatory actions; the extent and duration of the effects of the COVID-19 pandemic; litigation and investigations; business development transactions; economic conditions; and changes in laws and regulations, including health care reform. The company undertakes no duty to update forward-looking statements except as required by applicable law.

About Marksans Pharma:

Marksans Pharma Ltd. (www.marksanspharma.com) headquartered in Mumbai, India is engaged in the Research, Manufacturing & Marketing of generic pharmaceutical formulations in the global markets. The company's manufacturing facilities are approved by several leading regulatory agencies including USFDA, UKMHRA, and Australian TGA. The company's robust product portfolio spreads over major therapeutic segments of CVS, CNS, Antidiabetic, Pain Management, Gastroenterological, and Anti-allergies. The company is marketing these products globally.

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