



Ref: BHL/STEX 39/2025-26
Date: October 04, 2025

BSE Limited Phiroze Jeejeebhoy Towers Dalal Street Mumbai – 400 001	National Stock Exchange of India Limited 5 th Floor, Exchange Plaza, Bandra Kurla Complex Bandra (East) Mumbai-400051
Scrip Code: 539872	Symbol: BAJAJHCARE

Dear Sir/Madam,

Subject: Intimation under Regulation 30 of the SEBI (LODR) Regulations, 2015

We wish to inform you that Bajaj Healthcare Limited, has received recommendation from Subject Expert Committee (SEC) (Neurology & Psychiatry) of Central Drugs Standard Control Organisation (CDSCO) to conduct Phase III clinical trials for Suvorexant Tablets 5mg, 10mg, 50mg, 15mg & 20mg.

The press release in this regard, being issued by the Company is hereby submitted for your information.

Kindly acknowledge and take the same on record.

Thanking You,

**For and Behalf of Board of Director of
Bajaj Healthcare Limited**

**Monica Tanwar
Company Secretary & Compliance Officer**

Encl: as above



Investor Release

Bajaj Healthcare Limited Secures SEC-CDSCO Nod for Phase III Clinical Trials of Suvorexant Tablets

Mumbai, 04th Oct 2025: Bajaj Healthcare Limited is pleased to share that it has received a positive recommendation from the Subject Expert Committee (SEC) (Neurology & Psychiatry) of the Central Drugs Standard Control Organisation (CDSCO) to initiate Phase III clinical trials for Suvorexant Tablets, available in strengths of 5mg, 10mg, 15mg, and 20mg.

Notably, Bajaj Healthcare is the first company in India to receive this regulatory nod for Suvorexant, marking a pioneering step that reflects its long-standing experience and proven execution capabilities in drug development and clinical research. Suvorexant is a prescription medication used to treat insomnia in adults. It works by modulating the sleep-wake cycle through the central nervous system, promoting improved sleep onset and maintenance.

The upcoming Phase III trials will evaluate the efficacy, safety, and tolerability of Suvorexant in a diverse patient population, representing the final and most crucial step before regulatory submission. Upon successful completion, Bajaj Healthcare intends to pursue marketing authorization in select markets, paving the way for its commercial launch.

Speaking at the occasion Mr. Anil Jain, Managing Director, Bajaj Healthcare Limited, said - “We are encouraged by the SEC’s recommendation and remain committed to advancing Suvorexant through the final stages of clinical development. With our robust R&D infrastructure and GMP-compliant manufacturing capabilities, we are confident in our ability to deliver high-quality, impactful CNS solutions to patients worldwide. This development not only strengthens our neurology portfolio but also aligns with our strategic vision of addressing unmet medical needs in chronic and lifestyle-related disorders.”

About Bajaj Healthcare Ltd:

Bajaj Healthcare Limited a leading Manufacturer of APIs, Intermediates and Formulations. Established in the year 1993, it specializes in manufacturing of intermediates, API, formulations & Nutraceuticals. The Company has state-of-art manufacturing facilities of APIs, intermediates and formulations. These facilities are designed to meet the requirements of both advanced as well as emerging market opportunities. BHL has a strong presence globally in countries like Europe, USA, Australia, Middle East and South America.



Contact Details

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Safe Harbor Statement

Any forward-looking statements about expected future events, financial and operating results of the Company are based on certain assumptions which the Company does not guarantee the fulfilment of. These statements are subject to risks and uncertainties. Actual results might differ substantially or materially from those expressed or implied. Important developments that could affect the Company's operations include a downtrend in the industry, global or domestic or both, significant changes in political and economic environment in India or key markets abroad, tax laws, litigation, labour relations, exchange rate fluctuations, technological changes, investment and business income, cash flow projections, interest, and other costs. The Company does not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date thereof.