Press Release

Granules India Limited Secures Sole First-to-File ANDA Status for Sodium Oxybate Extended-Release for Oral Suspension

Hyderabad, India - July 6, 2026 — Granules India Limited announced that it has secured Sole First-to-File (FTF) status for its Abbreviated New Drug Application (ANDA) for Sodium Oxybate Extended-Release for Oral Suspension, the generic equivalent of LUMRYZ® extended-release oral suspension.

This achievement marks Granules' second Sole First-to-File ANDA, following its earlier success with Amphetamine Extended-Release Tablets, the generic equivalent of Dyanavel XR®, and further demonstrates the company's growing capabilities in developing and advancing complex, differentiated generic products for the U.S market.

"Securing Sole First-to-File status for our Sodium Oxybate Extended Release for Oral Suspension ANDA is another important milestone in our complex generics journey. This achievement reflects the strength of our R&D and regulatory capabilities, while reinforcing our commitment to building a differentiated portfolio. We remain focused on expanding patient access to affordable treatment options and delivering sustainable long-term growth."

— Dr. Krishna Prasad Chigurupati, Chairman & Managing Director, Granules India Limited

The Sole First-to-File designation further strengthens Granules position in the complex generics segment and underscores the Company's continued focus on innovation, execution excellence, and strategic portfolio expansion in regulated markets.

LUMRYZ® (sodium oxybate) extended-release oral suspension is indicated in the United States for the treatment of cataplexy or excessive daytime sleepiness in patients with narcolepsy. LUMRYZ® is a registered trademark of Alkermes plc or its affiliates.

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About Granules India Ltd. (BSE: 532482, NSE: GRANULES)

Granules India Limited, incorporated in 1991, is a vertically integrated, fast-growing Indian pharmaceutical company headquartered in Hyderabad, with best-in-class facilities and a commitment to operational excellence, quality, and customer service. We are among the few pharmaceutical companies in the world to be present across the entire manufacturing value chain — from Active Pharmaceutical Ingredients (APIs), Pharmaceutical Formulation Intermediates (PFIs), and Finished Dosages (FDs) to Peptides CDMO. Our products are distributed to more than 300 customers across regulated and semi-regulated markets, with a global presence extending to over 80 countries and offices across India, the US, and Switzerland. The Company has 10 manufacturing facilities, of which seven are in India, two are in the US, and one is in Switzerland, and has regulatory approvals from US FDA, EDQM, EU GMP, COFEPRIS, WHO GMP, TGA, K FDA, DEA, MCC, and HALAL.

For more information about Granules India Ltd. and its initiatives, please visit www.granulesindia.com.

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Media Contact:	**Investors Contact:**
Priyanka Chawla Corporate Communications priyanka.chawla@granulesindia.com	**Chaitanya Tummala** Company Secretary chaitanya.tummala@granulesindia.com