PRESS RELEASE





ZIM Laboratories Limited and Neuraxpharm Announce Grant of Marketing Authorization for "Buprenorphine Sublingual Film" in Europe

Nagpur, India and Barcelona, Spain and Düsseldorf, Germany, January 10th, 2025

ZIM Laboratories Limited (ZIM LABS), a specialty pharma R&D company focused on novel drug delivery systems, and Neuraxpharm Group (Neuraxpharm), a leading European specialty pharmaceutical company focused on the treatment of central nervous system (CNS) disorders, are pleased to announce that Committee for Medicinal Products for Human Use (CHMP) has granted Marketing Authorization (MA) to Neuraxpharm, for "Buprenorphine Sublingual Film" in Europe, co – developed by ZIM LABS using its patented oral thin-film technology.

Buprenorphine is indicated for the substitution treatment of opioid drug dependence. According to IQVIA, the European market for Buprenorphine-based opioid dependency treatments in 2023 surpassed USD 355 million annually, driven by increasing awareness and improved access to treatment programs. Further, the market size for Buprenorphine reached USD 1.3 billion in 2023.

Developed using ZIM LABS' proprietary oral thin-film technology, the sublingual film offers rapid dissolution under the tongue for faster therapeutic action and improved patient compliance. This advanced formulation minimizes risks associated with misuse, respiratory depression, and overdose, setting a new benchmark in patient safety. Buprenorphine Sublingual Film follows the co-development agreement in Europe of novel oral thin films (OTF) between ZIM LABS and Neuraxpharm announced in 2019.

Commenting on this significant milestone, Dr. Anwar Daud, Chairman & Managing Director of ZIM Laboratories Limited, said:

"The Marketing Authorisation granted for Buprenorphine sublingual films which has been codeveloped by ZIM LABS on its proprietary oral thin film technology, marks a pivotal moment in ZIM LABS' journey of innovation and partnership. It reflects the commitment of ZIM LABS to

advancing healthcare solutions that prioritize patient outcomes and safety while maintaining the highest regulatory standards. We look forward to commercialisation of this product in the European Market"

ZIM LABS Limited remains dedicated to pioneering advancements in drug delivery technologies, furthering its mission to address the evolving needs of patients and healthcare providers worldwide.

About ZIM Laboratories Limited:

ZIM Laboratories Limited is a research-driven pharmaceutical company that develops, manufactures, and supplies differentiated generic products in oral solid dosage forms across key therapeutic segments. With state-of-the-art in-house R&D capabilities, ZIM LABS offers innovative drug delivery solutions using proprietary technology platforms aimed at enhancing patient convenience and treatment adherence. The shares of ZIM LABS are listed with the National Stock Exchange of India Limited (NSE) and BSE Limited (BSE).

For more information, visit - https://www.zimlab.in/

About the Neuraxpharm Group

Neuraxpharm is a leading European specialty pharmaceutical company focused on the treatment of the central nervous system (CNS), including both psychiatric and neurological disorders. It has a unique understanding of the CNS market built over 35 years.

Neuraxpharm is constantly innovating, with new products and solutions to address unmet patient needs and is expanding its portfolio through its pipeline, partnerships, and acquisitions.

The company has c.1,000 employees and develops and commercializes CNS products through a direct presence in more than 20 countries in Europe, two in Latin America, one in the Middle East, and globally via partners in more than 50 countries. Neuraxpharm is backed by funds advised by Permira.

Neuraxpharm manufactures many of its pharmaceutical products at Neuraxpharm Pharmaceuticals (formerly Laboratorios Lesvi) in Spain.

For more information, please visit https://www.neuraxpharm.com