

Zydus and Daewoong Pharmaceutical announce exclusive licensing agreement for development and commercialization of Leuprolide Long-Acting Injectable in the U.S.

Ahmedabad, India and Seoul, South Korea – December 11, 2023 -- Zydus Worldwide DMCC, a wholly owned subsidiary of Zydus Lifesciences Ltd (including its subsidiaries hereafter referred to as “Zydus”) and Daewoong Pharmaceutical Co., Ltd. (KRX: 069620.KS), today announced that they have entered into an exclusive licensing agreement to co-develop and commercialize Leuprolide Acetate for Depot Suspension (RLD: Lupron Depot®, AbbVie) in six dosage strengths for the United States (US) market.

Under the terms of the agreement, Zydus will assume full responsibility for the clinical development and commercialization in the US market, and Daewoong will be responsible for the pre-clinical studies, production and supply of the product. Daewoong, utilizing its proprietary technology, will produce Leuprolide Acetate for Depot Suspension in its manufacturing facilities located in Osong, South Korea. The exclusive agreement also includes development, regulatory, and commercialization milestone payments based on the successful outcome. Additionally, this agreement also includes a profit share on future sales between the two companies.

By combining the unique strengths and expertise of both companies to develop and commercialize Leuprolide Acetate for Depot Suspension, Zydus and Daewoong are set to make a positive impact in the healthcare industry, ensuring accessibility, affordability, and enhanced patient empowerment.

Speaking about the development, Managing Director of Zydus Lifesciences Ltd., Dr. Sharvil Patel said, “Enabling access to affordable generic versions for patients in the US has been our ongoing commitment. This is an important milestone and we are happy to work with Daewoong for generic version of Lupron Depot, empowering patients with the access to a critical therapy. This is yet another step to strengthen the Zydus’ complex injectable portfolio.”

“Given the complexity, complex generic drug products like Lupron Depot do not exist to date and we aim to be the first company in manufacturing the generic version of this complex, long-acting injectable Lupron Depot product,” said Sengho Jeon, Chief Executive Officer, Daewoong Pharmaceutical. “We are delighted to enter into this exclusive licensing agreement with Zydus as part of our plan to develop and commercialize long-acting injectable of Leuprolide Acetate.”



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Dedicated To Life

Leuprolide acetate for depot suspension is a gonadotropin-releasing hormone (GnRH) agonist, a long-acting injectable product in a kit with a prefilled dual-chamber syringe, used for the treatment of advanced prostatic cancer, endometriosis, and uterine leiomyomata (fibroids) depending on its dosage regime. Leuprolide acetate for depot suspension had annual sales of approximately \$671 million in the US with a growth rate of 10%, according to IQVIA data MAT Oct-2023.

About Zydus

The Zydus Group with an overarching purpose of empowering people with freedom to live healthier and more fulfilled lives, is an innovative, global life-sciences group that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group employs over 25000 people worldwide and is driven by its mission to unlock new possibilities in life-sciences through quality healthcare solutions that impact lives. The group aspires to transform lives through path-breaking discoveries. For more details visit www.zyduslife.com

About Daewoong Pharmaceutical Co., Ltd.

Established in 1945, Daewoong Pharmaceutical Co., Ltd. is a leading South Korean pharmaceutical company that develops, manufactures, and commercializes pharmaceuticals for both domestic and international markets. With a strong and innovative in-house R&D and advanced manufacturing facilities, Daewoong provides a total healthcare solution to customers across the globe. Continuing on their course of building a strong global healthcare company, Daewoong has broadened international operations by establishing branch offices and research centers throughout Asia and the United States. Daewoong has also expanded strategic partnerships in more than 100 countries worldwide. For further information, visit the company's website at www.daewoong.co.kr/en

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