

Zydu and TLC sign agreement to market Liposomal Amphotericin B, a critical drug to treat Black Fungus or Mucormycosis in India

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Zydu, an innovation driven global pharma major and TLC, a specialty pharmaceutical company in Taiwan, today announced the signing of a license supply and commercialization agreement to commercialize AmphoTLC™ (Amphotericin B Liposome for Injection 50mg) in India. AmphoTLC™ is a critical drug to treat Mucormycosis or Black Fungus in India. Under the terms of the agreement, TLC will manufacture and supply AmphoTLC™ on a non-exclusive basis to Zydu, and Zydu will commercialize AmphoTLC™ in India.

The Central Drugs Standard Control Organization (CDSCO) of India has approved the New Drug Application (NDA) of TLC for Amphotericin B Liposome for Injection 50mg or AmphoTLC™ for immediate importation as per approved usage and indication. AmphoTLC™ is the first and only complex generic drug to have achieved bioequivalence to Gilead's AmBisome, proving its sameness to the safest form of amphotericin B in the world. With the surge of infections in India in the recent days AmphoTLC™ will address the country's acute liposomal amphotericin B shortage.

Mucormycosis is a serious fungal infection also known as black fungus, and COVID Associated Mucormycosis is a life-threatening form of mucormycosis which has emerged as a post-COVID complication, infecting about 30% of COVID patients who are diabetic or otherwise immunocompromised. If progression of the infection is not treated early, over 60% of patients could die. The increasing number of CAM cases has resulted in unprecedented demand for liposomal amphotericin B, the key drug to treat mucormycosis, causing an acute shortage of the drug.

AmphoTLC is a liposomal amphotericin B injection indicated for severe systemic fungal infections such as mucormycosis. The drug is approved in Taiwan and has been manufactured and sold by Yung Shin Pharmaceutical Industrial Co. (YSP) for several years. The approval of AmphoTLC™ in India follows the conduct of comprehensive due diligence by regulators in India based on the numerous years of development TLC has dedicated as well as its quality performance in the developed markets.

The steep increase in price and the financial burden it brings is forcing patients to opt for conventional amphotericin B, which is known for its nephrotoxicity, with many patients having to discontinue usage due to renal toxicities.

Speaking on the development, Dr. Sharvil Patel, Managing Director, of Cadila Healthcare Ltd, said, “With India facing an acute shortage of the drug to treat mucormycosis, we are making this critical drug available in India on an immediate basis. The need of the hour is to tackle this life-threatening infection with a safe and effective therapy.”

Commenting on the speed of the process, George Yeh, President of TLC, said, “We would like to thank Zydus for their quick action and cooperation in enabling a swift commercialization process. TLC is glad to be able to assist in the humanitarian crisis in such a quick fashion, and as our corporate tagline – Delivering Hope for Life™ – depicts, we will be delivering the first batch of AmphoTLC™ to India to help assuage the urgent need for one of the safest and most effective antifungal drugs very soon.”

About Zydus

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare therapies, including small molecule drugs, biologic therapeutics and vaccines. The group employs nearly 25,000 people worldwide, including 1,400 scientists engaged in R & D, and is dedicated to creating healthier communities globally. www.zyduscadila.com

About TLC

TLC (NASDAQ: TLC, TWO: 4152) is a clinical-stage, specialty pharmaceutical company dedicated to the research and development of novel nanomedicines that maximize the potential of its proprietary lipid-assembled drug delivery platform (LipAD™), including BioSeizer® sustained release technology and NanoX™ active drug loading technology, which are versatile in the choice of active pharmaceutical ingredients and scalable in manufacturing. TLC has a diverse, wholly owned portfolio of therapeutics targeting areas of unmet medical need in pain management, ophthalmology, oncology and infectious diseases. TLC is consistently ranked in the top 5% among all listed companies in Taiwan’s Corporate Governance Evaluations.