



TLC Announces Approval of New Drug Application of Liposomal Amphotericin B in India

SOUTH SAN FRANCISCO, CA and TAIPEI, Taiwan – May 25, 2021 – TLC (Nasdaq: TLC, TWO: 4152), a clinical-stage specialty pharmaceutical company developing novel nanomedicines to target areas of unmet medical need, today announced that the Central Drugs Standard Control Organization (CDSCO) of India has approved the New Drug Application (NDA) of Amphotericin B Liposome for Injection 50mg (known as Ampholipad® in Taiwan and AmphoTLC™ in India) for immediate importation per approved usage and indication, to aid in the country's emergency of acute liposomal amphotericin B shortage.

"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," commented George Yeh, President of TLC. "We are glad that the result of years of our hard work is able to help India in their times of need. With this approval and prompt delivery of our product, thousands of patients will have the opportunity to receive early treatment with AmphoTLC™, reducing the fatality rate brought on by the sudden influx of mucormycosis."

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 marketed and sold for several years, with a steady increase in market share each year; market authorization of the drug in China is under review. The approval of AmphoTLC™ in India follows the conduct of complete 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.

With a soaring number of COVID-19 infections in India, the number of COVID-19 associated mucormycosis (CAM) cases has also been on the rise. Mucormycosis is a serious fungal infection also known as black fungus, and CAM 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 unprecedentedly high demand for liposomal amphotericin B, the key drug to treat mucormycosis, causing an acute shortage of the drug. Exploitation by sellers on the black market, who are marking up the price of liposomal amphotericin B by three times, is further exacerbating the situation. 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.

In light of the ongoing COVID-19 pandemic situation and in response to the humanitarian crisis, the new drug registration for AmphoTLC™ was promptly granted



in India. The registration allows for immediate importation of AmphoTLC™ as per approved usage and indication of liposomal amphotericin B in India, which includes mucormycosis, to help alleviate the urgent need for the drug.

“We are glad to be lending a helping hand in conjunction with TLC in this dark hour, bringing a ray of light by delivering AmphoTLC™ to those in need to help them get over this severe infection,” commented Barbara Li, General Manager of Yung Shin Pharmaceutical Industrial Co., contract manufacturer for AmphoTLC™.

“TLC appreciates the support of Indian authorities who thoroughly and expeditiously granted the approval of AmphoTLC™,” commented Dr. Keelung Hong, Founder, Chairman and CEO of TLC. “We are pleased to be able to address the current emergency in India by fulfilling an unmet need for one of the safest and most effective drugs to treat COVID-19 patients afflicted with this debilitating infection, and we will start delivering shipments of AmphoTLC™ to India immediately.”

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.

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