



## TLC and Strides Enter Agreement for AmphoTLC™ in India

**SOUTH SAN FRANCISCO, CA, TAIPEI, Taiwan and BENGALURU, India – May 27, 2021** – **TLC** (Nasdaq: TLC, TWO: 4152), a clinical-stage specialty pharmaceutical company developing novel nanomedicines to target areas of unmet medical need, and **Strides Pharma Science Limited** (Strides, BSE: 532531, NSE: STAR), a global pharmaceutical company, have entered a license supply and commercialization agreement to commercialize AmphoTLC™ (Amphotericin B Liposome for Injection 50mg) in India.

Under the terms of the non-exclusive agreement, AmphoTLC™ supplied by TLC will be imported from Taiwan by **Stelis Biopharma Private Limited** (Stelis), the biotech arm of Strides group, and will be launched and distributed in India immediately by Strides.

TLC has obtained necessary approvals for AmphoTLC™ from regulatory authorities in India, including a new drug registration with India's Central Drugs Standard Control Organization (CDSCO) on May 25, 2021, for immediate importation as per approved usage and indication of liposomal amphotericin B.

"We are pleased to partner with TLC for the distribution of AmphoTLC™," commented Dr. R. Ananthanarayanan, CEO and Managing Director of Strides. "The approval from CDSCO has allowed us to immediately import and distribute the product in India and help ease the crisis arising out of an unprecedented rise in COVID-19 related mucormycosis cases. We have expanded our COVID-19 portfolio further with the TLC partnership and reinforced our effort and commitment to fight against this global pandemic."

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 recent surge of infections in India, AmphoTLC™ will address the country's acute liposomal amphotericin B shortage.

"We are pleased to see such swift action by the Indian regulatory authorities and our local partners to ensure availability of one of the safest and most efficacious antifungal drugs for the people," commented George Yeh, President of TLC. "We look forward to the imminent shipment of AmphoTLC™ within a few days' time."

### **About AmphoTLC™**

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 under the name Ampholipad®, 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.



### **About Mucormycosis**

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.

### **About Strides**

Strides, listed on the BSE Limited (532531) and National Stock Exchange of India Limited (STAR), is a global pharmaceutical company headquartered in Bengaluru, India. The Company mainly operates in the regulated markets and has an “in Africa for Africa” strategy along with an institutional business to service donor-funded markets. The Company’s global manufacturing sites are located in India (Chennai, Puducherry and two locations in Bengaluru), Singapore, Italy (Milan), Kenya (Nairobi) and the United States (Florida). The Company focusses on “difficult to manufacture” products that are sold in over 100 countries. Additional information is available at the Company’s website at [www.strides.com](http://www.strides.com).

### **About Stelis**

Stelis is a vertically integrated biopharmaceutical company. Stelis offers end-to-end state-of-the-art CDMO services across all phases of pre-clinical and clinical development and commercial supply of biologics. Its operations include R&D, process development, scale-up & end-to-end cGMP manufacturing capabilities from drug substance through drug product in all formats and packaging. Stelis is also developing select follow-on biologic products for global markets in niche and commercially attractive disease categories. Stelis has recently forayed into Vaccine manufacturing with a capability to do multiple vaccine types. Stelis’ state-of-the-art research & development facility and 200,000 sq. ft. fully integrated cGMP manufacturing facility are located in Bengaluru, India. Facilities cater to the development and cGMP manufacturing of biologics and injectables conforming to international standards. For more information visit [www.stelis.com](http://www.stelis.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<sup>®</sup>). TLC's deep experience with liposome science allows a combination of onset speed and benefit duration, improving active drug concentrations while decreasing unwanted systemic exposures. TLC's BioSeizer<sup>®</sup> technology is designed to enable local sustained release of therapeutic agents at the site of disease or injury; its NanoX<sup>®</sup> active drug loading technology has been proven in two approved drugs and is designed to alter the systemic exposure of a drug, potentially reducing dosing frequency and enhancing distribution of liposome-encapsulated active agents to the desired site. These technologies are versatile in the choice of active pharmaceutical ingredients, and scalable with respect to manufacturing. TLC has a diverse, wholly owned portfolio of therapeutics that target areas of unmet medical need in pain management, ophthalmology, and oncology. TLC is consistently ranked in the top 5% among all listed companies in Taiwan's Corporate Governance Evaluations. For more information, visit [www.tlcbio.com](http://www.tlcbio.com).

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