



May 27, 2021

BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street, Mumbai – 400 001
Scrip code: 532531

The National Stock Exchange of India Limited
Exchange Plaza, Bandra-Kurla Complex
Bandra (E) Mumbai - 400 051
Scrip code: STAR

Dear Madam/ Sir,

Sub: Press Release

Please find attached a Press Release issued by the Company titled:

“TLC and Strides partner to launch Liposomal Amphotericin B in India”

Thanks & Regards,
For **Strides Pharma Science Limited,**

A handwritten signature in blue ink that reads 'Manjula R.'.

Manjula Ramamurthy
Company Secretary



Encl. As above

Strides Pharma Science Limited

CIN: L24230MH1990PLC057062

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TLC and Strides partner to launch Liposomal Amphotericin B in India

- **TLC receives approval from Central Drugs Standard Control Organization of India to launch Amphotericin B Liposome for Injection 50mg**
- **Product to be manufactured in Taiwan, imported by Stelis Biopharma, and distributed in India by Strides Pharma Science Limited**
- **Launch to help alleviate the Liposomal Amphotericin B shortage arising due to recent surge in COVID-19 associated mucormycosis cases**

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, today announced that the Central Drugs Standard Control Organization (CDSCO) of India has approved TLC’s 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™ 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.

George Yeh, President, TLC, commented: *“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. We are glad that the result of years of our hard work can help India in its 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.”*

Dr R Ananthanarayanan, CEO and Managing Director, Strides, stated: *“We are pleased to partner with TLC for the distribution of liposomal amphotericin B. This approval from CDSCO allows 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.”*

Dr. Keelung Hong, Founder, Chairman and CEO, TLC, commented: *“TLC appreciates the support of Indian authorities who thoroughly and expeditiously approved AmphoTLC™. 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.”*

Barbara Li, General Manager, Yung Shin Pharmaceutical Industrial Co., the contract manufacturer for AmphoTLC™ commented: *“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.”*

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 the 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 and 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 the progression of 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, including mucormycosis, to help alleviate the urgent need for the drug.

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®). 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® technology is designed to enable local sustained release of therapeutic agents at the site of disease or injury; its NanoX® 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.

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

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

For further information, please contact:

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