



## **TLC and 3SBio Announce Acceptance of Marketing Authorization Application for Ampholipad™ in China**

**SOUTH SAN FRANCISCO, CA and TAIPEI, Taiwan – August 26, 2020 – [TLC](#)** (Nasdaq: TLC, TWO: 4152), a clinical-stage specialty pharmaceutical company developing novel nanomedicines to target areas of unmet medical need, in conjunction with [3SBio](#), today announced that the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA, formerly China Food and Drug Administration) has accepted its Marketing Authorization Application (MAA) for Ampholipad™, TLC's complex generic of Gilead's AmBisome® (amphotericin B liposome for injection) used for the treatment of systemic fungal infections. AmBisome® is currently not available in mainland China.

Ampholipad™, which has been approved and sold in Taiwan for many years, recently received a scale-up production approval, bumping its production to over a million vials a year. Ampholipad™ will be commercialized in mainland China by TLC's partner, 3SBio Inc. (HKEX: 1530), a fully integrated biotechnology company with high market penetration and a robust sales force whose operating revenue for 2019 exceeded RMB 5.3 billion (~US\$750 million). Under the terms of the partnership, TLC will receive a milestone payment for achieving this regulatory landmark.

"Despite the advancement of newer antifungal agents, amphotericin B remains the drug of choice for the treatment of most invasive fungal infections in immunocompromised patients, but toxicities of the conventional drug have been a concern," said Dr. George Spencer-Green, Chief Medical Officer of TLC and former clinical head of Pfizer's biosimilars development program. "While there are now several lipid-associated formulations of amphotericin B, most do not possess the unique pharmacokinetic and biodistribution profile attributed by the liposomal formulation of AmBisome®, which has demonstrated significantly lower incidences of nephrotoxicity and infusion-related chills/rigors compared to a lipid complex amphotericin B."

AmBisome's unavailability in China creates a rare opportunity for Ampholipad™ to become available before the brand drug.

"With the absence of AmBisome® in this region, China is uncharted territory for liposomal amphotericin B," said George Yeh, President of TLC. "TLC's Ampholipad™ has proven its sameness to the brand drug, and we believe the availability of Ampholipad™ may alter the current treatment landscape in China. We and our partner at 3SBio will continue communications with the CDE and hope to bring an effective and safer treatment to patients suffering from systemic fungal infections in the near future."



"3SBio is dedicated to seeking regulatory approvals for novel treatments to address unmet medical needs of Chinese patients," said Dr. Jing Lou, Chairman of 3SBio. "We will proactively prepare for the commercialization of Ampholipad™ in mainland China."

The huge commercial potential of Ampholipad™ is ensured by combining the advantages the lower toxicity of TLC's liposomal formulation and the strong sales and marketing team of 3SBio, with 3,000 professionals across China.

The MAA is supported by evidence of sameness demonstrated by clinical data in which Ampholipad™ demonstrated bioequivalence to AmBisome® in not only the total form and the encapsulated form plasma drug concentrations, but also in the un-encapsulated form, the most difficult standard to achieve, as well as by comprehensive chemistry and manufacturing control information which demonstrate pharmaceutical equivalence to AmBisome®.

According to research by Industrial Securities, sales of antifungal medications reached RMB3.4 billion in 2018, with an annual growth rate of 6.84%.

### **About TLC**

TLC (NASDAQ: TLC, TWO: 4152) is a clinical-stage specialty pharmaceutical company dedicated to the research and development of a diverse, wholly owned portfolio 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.

### **About 3SBio**

3SBio is a fully-integrated biotechnology company in China with market-leading biopharmaceutical franchises in oncology, auto-immune diseases, nephrology, metabolic diseases and dermatology. 3SBio is focusing on building an innovative product pipeline, currently with over 30 product candidates under development. 3SBio's manufacturing capabilities include recombinant proteins, monoclonal antibodies and chemically-synthesized molecules, with production centers in Shenyang, Shanghai, Hangzhou, Shenzhen and Cuomo, Italy. Please visit [www.3sbio.com](http://www.3sbio.com) for additional information.

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