TLC Announces Scale-up Production Approval for Ampholipad™

First and only AmBisome® generic to achieve bioequivalence in both small and large batches

SOUTH SAN FRANCISCO, CA and TAIPEI, Taiwan – June 21, 2020 – TLC (Nasdaq: TLC, TWO: 4152), a clinical-stage specialty pharmaceutical company developing novel nanomedicines to target areas of unmet medical need in pain management, ophthalmology and oncology, today announced that the Taiwan Food and Drug Administration (TFDA) has officially approved the company's Scale-up & Post-approval Changes application for Ampholipad™, a generic liposomal amphotericin B drug for the treatment of systemic fungal infections. The approval comes after TLC successfully demonstrated bioequivalence of Ampholipad™ to AmBisome® in all three forms and in both large and small batches, making Ampholipad™ the first and only drug to have achieved such a feat. Scaled-up production of Ampholipad™ can surpass a million vials each year, at a capacity capable of meeting increasing global demands.

According to The Lancet, fungal infections affect more than a billion people each year, resulting in approximately 11.5 million life-threatening infections and more than 1.5 million deaths annually. Gilead Sciences' AmBisome® (liposomal amphotericin B) is the most popular antifungal medication used for serious fungal infections and leishmaniasis, with global sales reaching US$420 million in 2018. Although 23 years have passed since AmBisome® first entered the market, a generic version has yet to been seen in China, Europe, and the US due to its complex formulation and chemistry and manufacturing control techniques. TLC's Ampholipad™ Liposome for Injection 50mg, a generic of AmBisome®, has been approved and marketed in Taiwan for more than six years.

In 2013, the TFDA approved TLC's abbreviated new drug application (ANDA) application for Ampholipad™ based on a smaller batch and gave it a health insurance price of around NT$6,000 (~US$200). With increasing international market demands, TLC made the decision to increase its production. As Ampholipad™ is a unique liposomal formulation generic whose manufacturing process is drastically more complex than small molecule drugs, regulations require that such post-approval scale-up changes must be supported by an additional bioequivalence study in conjunction with comprehensive chemistry and manufacturing control information. As such, TLC completed another bioequivalence study using the scaled-up batch, 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. The sameness between Ampholipad™ and AmBisome®, including liposome characteristics, has thus been confirmed.

"People now have the option of choosing a generic with the same quality as the branded drug, and TLC is the only company capable of providing such a generic," said

George Yeh, President of TLC. “Moving forward, we will work to gain approval of Ampholipad™ in global markets, making this product available in China, Europe, and the US.”

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.

Contact:

Dawn Chi
Corporate Communications
dawn@tlcbio.com