Press Release

TLC Announces Positive End-of-Phase II Meeting with FDA for TLC599 in Knee Osteoarthritis

Expects to initiate a single pivotal Phase III trial in mid-2019

SOUTH SAN FRANCISCO, CA and TAIPEI, Taiwan – April 15, 2019 – TLC (Nasdaq: TLC, TWO: 4152), a clinical-stage specialty pharmaceutical company dedicated to the development and commercialization of novel nanomedicines designed to target areas of unmet medical need in osteoarthritis, pain management, ophthalmology and oncology, today announced the successful completion of its End-of-Phase II meeting with the U.S. Food and Drug Administration (FDA) on receiving guidance, and discussing the clinical and regulatory pathway for a potential U.S. approval of TLC599, a BioSeizer® liposomal formulation of dexamethasone sodium phosphate for the treatment of knee osteoarthritis. In agreement with the FDA, the Company believes its proposed overall design of a single global pivotal Phase III trial will be sufficient to support a New Drug Application (NDA) submission. TLC expects to initiate the Phase III trial in mid-2019.

"We are pleased with the positive outcome from this meeting, where we and the FDA were aligned on the elements for our pivotal Phase III trial design," said TLC Chief Medical Officer Dr. George Spencer-Green, MD. "Feedback provided by the agency in the meeting minutes that we have received gives us further confidence that TLC599 is well-positioned for an approval pathway. Our pivotal trial will have a design similar to that of our Phase II trial, with the same level of comprehensiveness and inclusivity and an expanded patient population."

The Phase III clinical trial will be a global, randomized, double-blind, placebo- and active-controlled study to evaluate the safety and efficacy of a single dose – as well as repeated doses – of TLC599 in patients with knee osteoarthritis. Approximately 500 patients will be randomized into three groups at a 2:1:1 ratio, with each group receiving TLC599 12mg, DSP 4mg (active control), or saline (placebo), respectively. Key endpoints will include change from baseline in the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain and function scores, as well as Patient Global Impression of Change (PGIC) at various time points.

"We had a productive and collaborative meeting with the FDA and received valuable guidance which indicated that a single pivotal trial would be sufficient for a potential NDA submission in the U.S.," commented TLC President George Yeh. "Having this clear path forward for TLC599 is an exciting and important milestone for our company and also encouraging for other clinical programs in our pipeline."

This End-of-Phase II meeting took place following positive results from a successfully completed Phase II clinical trial, which evaluated the safety and efficacy of a single intra-articular injection of TLC599 against placebo in patients with knee osteoarthritis through 24 weeks. Results from this trial showed statistically significant improvement in pain relief compared to placebo from Day 3 through Weeks 12, 16, 20, and 24 as well as at every scheduled visit. A majority of patients in the TLC599 group were clinically durable responders, maintaining at least 30% reduction in pain from baseline at all visits through Week 24.

About TLC599

TLC599 is a BioSeizer sustained release formulation of dexamethasone sodium phosphate (DSP) intended for the treatment of osteoarthritis (OA) pain. OA is a joint disorder involving the degeneration of the articular cartilage that leads to inflammation of the soft tissue and bony structures of the joint. Current intraarticular sustained release anti-inflammatory treatments for OA have potentially toxic side effects and may lead to the destruction of cartilage filler proteins. An *in vivo* toxicity study by staining of the cartilage showed TLC599 to be cartilage sparing

compared to current treatments. In its Phase II clinical trial, TLC599 was well-tolerated, fast-acting, and demonstrated statistically significant and clinically meaningful improvement in pain relief compared to placebo from Day 3 through Weeks 12, 16, 20 and 24.

About TLC

Taiwan Liposome Company, Ltd. ("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 believes that its deep experience with liposome science allows TLC to combine onset speed and benefit duration, and improve 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 is designed to alter the systemic exposure of the 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.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements contained in this press release include, without limitation, statements regarding TLC's expectations regarding the clinical development of TLC599, the clinical benefits of TLC599 for knee osteoarthritis, the timing, scope, progress and outcome of the clinical trials, and the anticipated timelines for the release of clinical data. Words such as "may," "believe," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are not guarantees of future performance and involve a number of risks, assumptions, uncertainties and factors, including risks that the outcome of any clinical trial is inherently uncertain and TLC599 or any of our other product candidates may prove to be unsafe or ineffective, or may not achieve commercial approval. Other risks are described in the Risk Factors section of TLC's prospectus dated November 21, 2018 filed pursuant to Rule 424(b)(4) with the U.S. Securities and Exchange Commission. All forward-looking statements are based on TLC's expectations and assumptions as of the date of this press release. Actual results may differ materially from these forward-looking statements. Except as required by law, TLC expressly disclaims any responsibility to update any forward-looking statement contained herein, whether as a result of new information, future events or otherwise.

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