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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 6-K**

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**REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13a-16 OR 15d-16  
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

**For the Month of October 2019**

**Commission File Number: 001-38746**

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**Taiwan Liposome Company, Ltd.**

(Translation of registrant's name into English)

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**Taiwan Liposome Company, Ltd.**  
11F-1, No. 3 Yuanqu Street  
Nangang District,  
Taipei City, Taiwan 11503  
(Address of principal executive office)

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Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F  Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

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**Announcement of initiation of Phase III pivotal clinical trial of TLC599 for the treatment of osteoarthritis knee pain**

In October 2019, Taiwan Liposome Company, Ltd. (the “Company”) issued a press release announcing initiation of Phase III pivotal clinical trial of TLC599 for the treatment of osteoarthritis knee pain.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

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**Exhibits**

**Exhibit  
Number**

**Exhibit Description**

99.1

[Press release, dated October 1, 2019, entitled "TLC Announces Initiation of Phase III Pivotal Clinical Trial of TLC599 for the Treatment of Osteoarthritis Knee Pain."](#)

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**TAIWAN LIPOSOME COMPANY, LTD.**

Date: October 1, 2019

By: /s/ George Yeh

Name: George Yeh

Title: President



## TLC Announces Initiation of Phase III Pivotal Clinical Trial of TLC599 for the Treatment of Osteoarthritis Knee Pain

- Phase II results showed statistically significant pain relief through 24 weeks
- Phase III to evaluate efficacy of single and repeated doses up to 52 weeks

**SOUTH SAN FRANCISCO, CA and TAIPEI, Taiwan – October 1, 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 pain management, ophthalmology and oncology, today announced the initiation of a Phase III clinical trial (“EXCELLENCE”) to evaluate the efficacy and safety of single as well as repeated doses of TLC599 in patients with osteoarthritis (OA) of the knee. TLC599 is a BioSeizer® sustained release formulation of dexamethasone sodium phosphate (DSP) intended for the management of OA pain.

In the Phase II clinical trial, a single intraarticular injection of TLC599 resulted in statistically significant and clinically meaningful improvement in pain relief in both the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and Visual Analog Scale (VAS) scores compared to placebo from Day 3 all the way through the end of the study at 24 weeks. Over half of the patients in the TLC599 group had a durable response, maintaining at least 30% pain reduction in both WOMAC and VAS pain scores at all visits through the entire 24 weeks.

EXCELLENCE is a multi-center, randomized, double-blind, placebo- and active comparator-controlled pivotal study that will treat approximately 500 knee OA patients at 40-50 sites in the US and Australia.

“The initiation of EXCELLENCE, which was carefully designed in alignment with guidance from the US Food and Drug Administration (FDA), marks a significant milestone for both TLC and the millions of people suffering from knee OA,” said George Yeh, President of TLC. “We are pleased to have arrived at this pivotal moment, as we believe TLC599, which provided immediate as well as prolonged pain relief in previous clinical studies, has the potential to be an effective therapy, eluding pain and delivering a better quality of life to patients who are still in search of better treatment options.”

OA is the most prevalent joint disease and a leading source of chronic pain and disability in the United States and other developed nations. Knee OA accounts for more than 80% of the disease’s total burden and affects at least 19% of American adults aged 45 years and older.

### **About EXCELLENCE**

EXCELLENCE, a Phase III, randomized, double-blinded, placebo- and active comparator-controlled pivotal study, will evaluate the safety and efficacy of single and



repeat doses of TLC599 in patients with knee OA of Kellgren-Lawrence Grade 2 to 3 severity across 40-50 sites in the United States and Australia. The study will enroll approximately 500 patients who are randomized in a 2:1:1 ratio to receive TLC599, DSP, or saline placebo via intraarticular injection. The primary efficacy endpoint for the first injection is the magnitude of pain relief by WOMAC Pain score versus placebo at Week 16. Secondary endpoints include the magnitude of pain relief by WOMAC Pain or Function scores versus placebo or DSP at Weeks 16, 20, and 24, and patient global impression of change (PGIC). At Week 24, eligible patients will receive a blinded second injection of TLC599 or placebo. Patients will be followed up for a total of 52 weeks.

### **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 believes that its 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 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.

### **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



annual report on Form 20-F for the year ended December 31, 2018 filed 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.

#### **References**

- Murray CJ, *et al.* (2013) The state of US health, 1990-2010: Burden of diseases, injuries, and risk factors. *JAMA* **310**:591–608.
- Vos T, *et al.* (2012) Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990-2010: A systematic analysis for the Global Burden of Disease Study 2010. *Lancet* **380**:2163–2196.
- Lawrence RC, *et al.* (2008) Estimates of the prevalence of arthritis and other rheumatic conditions in the United States. Part II. *Arthritis Rheum* **58**:26–35.

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