



## **TLC Announces Early Completion of Patient Enrollment in TLC590 Phase II Clinical Trial following Bunionectomy**

*Topline results on the analgesic efficacy of TLC590 for postsurgical pain management following the hard tissue surgery are expected in mid-2020*

**SOUTH SAN FRANCISCO, CA and TAIPEI, Taiwan – February 12, 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 the earlier-than-scheduled completion of patient enrollment in Part 2 of the [TLC590](#) Phase II clinical trial, which is taking place across four sites in the United States. The randomized, double-blind, comparator- and placebo-controlled study will evaluate the analgesic efficacy and safety of TLC590 for postsurgical pain management in patients following bunionectomy. Topline data is expected to be reported in mid-2020.

TLC590 is a non-opioid, proprietary [BioSeizer<sup>®</sup>](#) sustained release formulation of ropivacaine intended to manage postsurgical pain for three days or more with a single dose, potentially reducing the need for opioids following surgery.

In Part 1 of the two-part Phase II clinical trial following bunionectomy, the safety, dose linearity and relative bioavailability of TLC590 were established based on 50 patients.

In Part 2, an efficacy and safety study, 150 patients have been randomized at the ratio of 1:1:1 to receive a single infiltrative local dose of TLC590 228mg, bupivacaine 50mg or normal saline placebo at the end of their bunionectomy surgery. All patients are closely monitored for an inpatient period of 72 hours, and then followed up through 42 days after surgery. The primary endpoint is area under the curve (AUC) from 0 to 72 hours on the numerical pain rating scale. Secondary endpoints include proportion of pain-free patients, proportion of opioid-free patients, and total post-operative opioid consumption at various time periods, plus time to the first post-operative use of opioids.

“We are pleased to have completed enrollment of all patients well ahead of schedule,” said George Yeh, President of TLC. “We look forward to seeing the data as well as the subsequent results, which are expected in the middle of this year. If results are positive, data from this Phase II trial and the previous Phase I/II trial in patients following hernia repair surgery will give us the confidence to proceed into Phase III clinical trials.”

### **About TLC590**

TLC590 is a non-opioid, BioSeizer<sup>®</sup> sustained release formulation of ropivacaine designed to prolong the retention time of ropivacaine around the injection site as a drug depot, simultaneously extending its therapeutic period and reducing unwanted



systemic exposure. In a Phase I/II, randomized, double-blind, comparator-controlled dose escalation study of 64 patients following hernia repair surgery (a type of soft tissue surgical operation), TLC590 demonstrated statistically significant and clinically meaningful reductions in pain intensity with movement over ropivacaine as measured by  $AUC_{0-24h}$  ( $p=0.0057$ ),  $AUC_{0-48h}$  ( $p=0.0131$ ),  $AUC_{0-72h}$  ( $p=0.0117$ ) and  $AUC_{0-96h}$  ( $p=0.0103$ ). Time to first opioid use in the TLC590 group was four times that of the ropivacaine group. Mean total opioid consumption through 96 hours post-surgery in the TLC590 group was 54% less than the ropivacaine group. A Phase II, randomized, double-blind, comparator- and placebo-controlled study following bunionectomy (a type of hard tissue, or bony, surgical operation) has completed patient enrollment; data is expected mid-2020.

### **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<sup>®</sup>). 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<sup>®</sup> technology is designed to enable local sustained release of therapeutic agents at the site of disease or injury; its NanoX<sup>™</sup> 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.

### **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 TLC590, the clinical benefits of TLC590 for postsurgical pain management, 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 TLC590 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.

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