TLC Announces Topline Results for TLC590 Phase II Trial for Postsurgical Pain Management following Bunionectomy

SOUTH SAN FRANCISCO, CA and TAIPEI, Taiwan – May 31, 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 topline results from the TLC590 Phase II clinical trial, a randomized, double-blind, placebo- and comparator- controlled study of TLC590 in patients following bunionectomy. Results show that TLC590 demonstrated greater reductions in pain than both placebo and bupivacaine through 168 hours.

TLC590 is a non-opioid, proprietary BioSeizer® sustained release formulation of ropivacaine. The trial compared TLC590 (228mg) with normal saline placebo and the current standard of care for postsurgical pain relief, bupivacaine (50mg), in 150 patients randomized at the ratio of 1:1:1. The primary outcome measure was comparison of pain relief between TLC590, placebo, and bupivacaine in area under the curve (AUC) on the numerical pain rating scale (NPRS).

Key findings from the trial are as follows:

- The overall reduction in pain intensity provided by TLC590 was greater than that of placebo as well as bupivacaine at every time interval from 0 hours through the end of the study at 168 hours.
- TLC590 achieved statistically significant pain relief over both placebo ($p<0.001$) and bupivacaine ($p=0.0188$) from 0 to 24 hours. The differences in AUC_{0-72} did not reach statistical significance.
- TLC590 delayed the median time to first post-operative opioid use, and the total post-operative opioid consumption of TLC590 was less than both placebo and bupivacaine at every time point through 168 hours.
- TLC590 was well-tolerated, with a safety profile comparable to bupivacaine and placebo. Most adverse events were mild and unrelated to the treatment. There were no serious adverse events in the TLC590 group.

“We continue to be excited about TLC590 as we observed a promising trend in this small patient population, similar to what we saw in our Phase I/II clinical trial in patients following hernia repair surgery, and we believe that in an expanded patient population, this drug will demonstrate significant clinical benefits beyond 24 hours in our upcoming pivotal trials,” said TLC President George Yeh. “We will continue to analyze the data and work closely with regulatory bodies to efficiently bring TLC590 to market. TLC is committed to presenting a fast onset, long-lasting, single-dose non-opioid treatment that can potentially reduce the need for opioids while helping patients cope with the pain experienced after surgery.”

Details of TLC590’s clinical trials can be found on ClinicalTrials.gov.

About TLC590

TLC590 is a non-opioid, BioSeizer® 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, TLC590 demonstrated statistically significant and clinically meaningful reductions in pain intensity with movement over ropivacaine as measured by AUC_{0-24} ($p=0.0057$), AUC_{0-48} ($p=0.0131$), AUC_{0-72} ($p=0.0117$) and AUC_{0-96} ($p=0.0103$). 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.

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.

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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