



TLC Presents Clinical and Preclinical Data of TLC590 at ANESTHESIOLOGY® Annual Meeting and in International Journal of Nanomedicine

TLC590 showed faster and longer lasting pain relief than ropivacaine

SOUTH SAN FRANCISCO, CA and TAIPEI, Taiwan – October 21, 2019 – [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, recently presented data at the [American Society of Anesthesiologists \(ASA\) ANESTHESIOLOGY® annual meeting](#) from a Phase I/II clinical trial which showed [TLC590](#) to yield more immediate and long-lasting pain reduction than ropivacaine. In addition, *in vivo* findings in which TLC590 showed no dose-related toxicity and other preclinical data were recently published in the [International Journal of Nanomedicine](#). TLC590 is a non-opioid, BioSeizer® formulation of ropivacaine with the aim to manage postsurgical pain for four to seven days with a single dose, potentially deterring the use of opioids following surgery.

At ANESTHESIOLOGY® 2019, which took place October 19-23 at the Orange County Convention Center in Orlando, FL, principal investigator Todd Bertoch, MD, Chief Medical Officer at JBR Clinical Research, a CenExel Clinical Research Center of Excellence, presented findings from a Phase I/II, randomized, double-blind, comparator-controlled, dose-escalation study of TLC590 following inguinal hernia repair.

Highlights from the [e-poster presentation](#) are as follows:

- TLC590 showed similar safety and tolerability as ropivacaine with no local anesthetic systemic toxicity (LAST) events; the incidence of probable opioid-related adverse events was lower in each TLC590 dose group than in the ropivacaine group.
- TLC590 displayed highly dose-linear pharmacokinetics in C_{max} and AUC; all doses of TLC590 had a lower C_{max} than the ropivacaine group, suggesting decreased potential for LAST.
- Each dose group of TLC590 reduced more pain than the ropivacaine group, both with movement and at rest; pain reduction was maintained through 168 hours.
- TLC590 reduced or eliminated the use of opioids: 58.3% of patients in the TLC590 475mg group did not use any opioids throughout the study; mean total opioid consumption was 54% less than that of the ropivacaine group through 96 hours post-surgery.

“I am delighted to have had the opportunity to present these fantastic results,” said Dr. Todd Bertoch. “As a clinical researcher specializing in pain, it is so rewarding to be able to share findings that provide hope for a real, substantive weapon in the war



against opioids. Clinicians have been waiting patiently for safe, easily administered, very long acting local anesthetics with a rapid onset. These data suggest that we may have found one.”

Results of studies evaluating the release profile of TLC590 *in vitro* and its pharmacokinetics and anesthetic effect *in vivo* were recently published in the International Journal of Nanomedicine.

Highlights from the [publication article](#) are as follows:

- TLC590 demonstrated a sustained release profile *in vitro*, with a half-life ten times longer than ropivacaine.
- TLC590 provided prolonged analgesic effect compared to ropivacaine in a guinea pig pin-prick wheal model.
- TLC590 was well tolerated; at a dose level of 20mg/kg in rats, there were no observable changes in body weight, organ weight, or hematology and serum chemistry analyses.

The poster presentation and full text article can be accessed under “Publications” in the Pressroom section of TLC’s website at www.tlcbio.com.

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. A Phase II, randomized, double-blind, comparator- and placebo-controlled clinical trial to evaluate the safety, pharmacokinetics and efficacy of TLC590 following bunionectomy is ongoing.

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 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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