



## **TLC Highlights Findings in Abstract Accepted at Osteoarthritis Research Society International (OARSI) 2020 and Published in *Osteoarthritis and Cartilage***

*Subgroup analyses of Phase II data confirm robustness of TLC599's efficacy response of greater pain reductions than placebo through 24 weeks*

**SOUTH SAN FRANCISCO, CA and TAIPEI, Taiwan – May 18, 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 publication of data from subgroup analyses from the Phase II clinical trial of [TLC599](#) in patients with osteoarthritis (OA) knee pain, which showed that the pattern of efficacy seen in the overall population, with greater reductions in pain with TLC599 than with placebo that sustained from Week 1 through Week 24, was remarkably consistent between the various subgroups. These findings were accepted as an abstract at [Osteoarthritis Research Society International \(OARSI\) 2020](#) and published in the [Osteoarthritis and Cartilage](#) journal (#722).

"We are happy to see that results of the subgroup analyses are consistent with our primary efficacy data," said George Yeh, President of TLC. "These findings further substantiate the robustness of the potential therapeutic effects that TLC599 has in extensively alleviating pain and discomfort across different segments of the population with osteoarthritis, a disease that affects over 300 million adults worldwide."

TLC599 is a [BioSeizer®](#) sustained release formulation of dexamethasone sodium phosphate. In a primary intent-to-treat analysis of a Phase II multi-center, randomized, double-blind, placebo-controlled clinical trial, a single intraarticular dose of TLC599 12mg demonstrated significant and durable pain relief and improved function compared to placebo over 24 weeks in patients with knee OA pain. To examine the robustness of this efficacy response, the changes in pain from baseline in subgroups of the intent-to-treat population were analyzed. Subgroups were categorized based on gender (male or female), age (50-65 years or 65+ years), Kellgren-Lawrence (K-L Grade 2 or Grade 3), pain in one or both knees (unilateral or bilateral), baseline Visual Analog Scale (VAS) pain scores (<7 or ≥7), and baseline Western Ontario and McMaster Universities Index (WOMAC) pain scores (<1.2 or ≥1.2). The pattern of durable pain reduction with TLC599 was generally consistent across all subgroups, with drastic reductions in pain by the first visit (Week 1) which maintained through the 24-week duration of the trial.

### **About TLC599**

Current intraarticular 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 a Phase II clinical trial, a single injection of TLC599 resulted in



statistically significant and clinically meaningful improvement in pain relief in both WOMAC and VAS scores over placebo for 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 24 weeks. EXCELLENCE, a multi-center, randomized, double-blind, placebo- and active comparator-controlled pivotal Phase III clinical trial to evaluate the efficacy and safety of both single and repeated doses of TLC599, is ongoing.

### **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.

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