Delivering Hope for Life™

TLC BioSciences Announces Publication of TLC599 Phase II Results in Arthritis Research & Therapy

March 7, 2022

TLC599 reduces pain and improves function for up to 24 weeks, longer than existing intraarticular treatments, and significantly reduces oral medication use

SOUTH SAN FRANCISCO, Calif. and TAIPEI, Taiwan, March 07, 2022 (GLOBE NEWSWIRE) -- TLC BioSciences, a clinical-stage specialty pharmaceutical company developing novel nanomedicines to target areas of unmet medical need, today announced that detailed results of its TLC599 Phase 2 clinical trial in patients with osteoarthritis of the knee have been published in the peer-reviewed journal *Arthritis Research & Therapy*. TLC599 is a proprietary BioSeizer® sustained release formulation of dexamethasone sodium phosphate (DSP) intended for the treatment of osteoarthritis pain. The results demonstrated statistically significantly reduced pain scores and oral pain medication use for up to 6 months with TLC599.

The Phase 2, multicenter, randomized, double-blind, placebo-controlled clinical trial was conducted in 75 patients with osteoarthritis of the knee. Patients were randomized and administered a single intraarticular injection of TLC599 or placebo and assessed for efficacy and safety for 24 weeks. Patient-reported outcomes included the Western Ontario and McMaster Universities Arthritis (WOMAC) Index for pain and function and visual analog scale (VAS) for pain. Acetaminophen was permitted as the only pain rescue medication; other pain medications including NSAIDs and opioids were not permitted.

Results showed that TLC599 demonstrated statistically significantly greater reduction in WOMAC pain and function as well as VAS scores compared to placebo through 24 weeks. Acetaminophen use in the TLC599 group was statistically significantly lower than that of the placebo group at most time points.

"Acetaminophen is a mild analgesic with little meaningful clinical benefit and real risks of harm, and the American Academy of Orthopedic Surgeons suggests no more than 3000mg per day to minimize its risk of liver damage," said Dr. David Hunter, lead author of the manuscript and professor of medicine at University of Sydney. "As patients in the TLC599 group were observed to consume significantly less acetaminophen than the placebo group, TLC599 has the potential to reduce the need for oral medication use in a setting where opioids are frequently resorted to for pain control."

The research article, titled "TLC599 in patients with osteoarthritis of the knee: a phase IIa, randomized, placebo-controlled, dose-finding study", is available on *Arthritis Research & Therapy*. The publication is an international peer-reviewed journal publishing original articles in musculoskeletal research and therapy.

"The US Centers for Disease Control and Prevention is proposing new guidelines for treating acute and chronic pain, recommending that doctors should first turn to nonopioid therapies wherever possible," said George Yeh, President of TLC BioSciences. "We believe that our Phase 2 as well as imminent Phase 3 results will show TLC599 to be an opportune nonopioid therapy for the treatment of chronic osteoarthritis pain."

EXCELLENCE, a Phase 3, multicenter, randomized, double-blind, placebo- and active comparator-controlled pivotal study evaluating the efficacy and safety of a single as well as a repeat dose of TLC599 in approximately 500 patients with knee osteoarthritis, has completed the last patient's last visit. Results from EXCELLENCE are expected this year.

About TLC BioSciences

TLC BioSciences 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's 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 Nano*X*® 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, infectious diseases, ophthalmology, and oncology.

Contact
Dawn Chi
Corporate Communications
dawn@tlcbio.com

tlc BIOSCIENCES

Source: TLC