



TLC Announces TLC599 Agreement with Endo

One of the largest deals seen in Taiwan's biotech sector

SOUTH SAN FRANCISCO, CA and TAIPEI, Taiwan – June 13, 2022 – TLC BioSciences (TLC), a clinical-stage specialty pharmaceutical company developing novel nanomedicines to target areas of unmet medical need, today announced that it has entered a commercialization agreement with **Endo International plc** (Nasdaq: ENDP) for rights in the United States to TLC599, a proprietary BioSeizer[®] sustained release injectable in Phase 3 development for the treatment of osteoarthritis pain.

Under the terms of the agreement, signed with Endo's subsidiary Endo Ventures Limited (EVL), TLC will primarily be responsible for the development of the product and EVL will primarily be responsible for obtaining regulatory approval and commercialization of the product in the United States. Upon receipt of regulatory approval, Endo will have exclusive rights to manufacture, market, sell and distribute the product in the United States. TLC will receive an upfront payment of \$30 million and will be eligible to receive up to an additional \$110 million based on the achievement of certain development, regulatory, and manufacturing milestones related to the initial indication for the treatment of osteoarthritis knee pain. TLC will be eligible to receive payments based on the achievement of certain commercial milestones and royalties based on the product's net sales in the United States. Additionally, TLC will be eligible to receive certain milestone payments for potential future indications.

"We are thrilled to be partnering with Endo once again," said George Yeh, President of TLC. "Endo's proven capabilities in the orthopedic space complement TLC's expertise in developing novel nanomedicines, and together, we hope to deliver life-enhancing therapies to meet an unmet need with a large patient base."

"TLC599 is fully aligned with our commitment to providing differentiated nonsurgical options to healthcare providers and their appropriate patients," said Patrick Barry, Executive Vice President and President, Global Commercial Operations at Endo. "This investigational product is highly synergistic with our existing orthopedic commercial capabilities and complements our current on-market and in-development orthopedic-focused opportunities."

"We are pleased to be adding another TLC product to Endo's portfolio," said Blaise Coleman, President and Chief Executive Officer at Endo. "We see tremendous



opportunity in TLC599 to potentially address an unmet medical need in patients with osteoarthritis arthritis knee pain. If approved, we expect to launch this differentiated branded product in 2025.”

About Osteoarthritis

OA is the most common form of arthritis, affecting an estimated 32.5 million adults in the United States, according to the Centers for Disease Control and Prevention.¹ Although OA can occur in any joints, it occurs most frequently in the hands, hips and knees. With OA, joint cartilage becomes worn and breaks down, and as a result, the bone surfaces can grind together and eventually begin to change. Common symptoms of OA include pain, stiffness and swelling, and they can worsen over time. In some cases, OA also can cause reduced function and disability. There is no cure for OA; however, symptom management options include behavior modification, drug therapy (oral, topical and injections within the joint) and knee replacement surgery.

About TLC599

TLC 599 is an extended and controlled release liposomal formulated dexamethasone for chronic knee osteoarthritis (OA) pain. Single and repeated doses of current intraarticular anti-inflammatory treatments for OA have potentially toxic side effects and may lead to the destruction of cartilage filler proteins. Preclinical toxicity studies showed no marked cartilage damage after single and multiple doses of TLC599 when compared to current treatments. In a Phase II clinical trial, a single injection of TLC599 resulted in statistically significant and clinically meaningful improvement in WOMAC Pain and Function Subscales, and VAS Pain scores over placebo at 12, 16 and 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. No serious or unexpected treatment related adverse events were reported, and most of the treatment related adverse events were mild to moderate in severity. EXCELLENCE, a pivotal Phase III clinical trial to evaluate the efficacy and safety of both single and repeated doses of TLC599, is nearing completion, with the last patient’s last visit having taken place in January 2022. The compound may be investigated in the future for additional potential indications.



About Endo

Endo (NASDAQ: ENDP) is a specialty pharmaceutical company committed to helping everyone we serve live their best life through the delivery of quality, life-enhancing therapies. Our decades of proven success come from passionate team members around the globe collaborating to bring the best treatments forward. Together, we boldly transform insights into treatments benefiting those who need them, when they need them. Learn more at www.endo.com or connect with us on [LinkedIn](#).

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 platforms (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 NanoX[®] 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.

References

- I. Centers for Disease Control and Prevention. (July 2020). *Osteoarthritis (OA)*. U.S. Department of Health and Human Services.
<https://www.cdc.gov/arthritis/basics/osteoarthritis.htm>. Accessed on May 20, 2022.

Contact

Dawn Chi
Corporate Communications
dawn@tlcbio.com