



Endo Executes Agreement With TLC to Commercialize Phase 3 Orthopedic Product for the Treatment of Osteoarthritis Knee Pain

June 13, 2022

DUBLIN, June 13, 2022 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) announced today that its subsidiary Endo Ventures Limited (EVL) has executed an agreement with Taiwan Liposome Company, Ltd. (TLC), a clinical-stage specialty pharmaceutical company developing novel nanomedicines to target areas of unmet medical need, to commercialize TLC599, a TLC investigational product. TLC599 is an injectable compound in Phase 3 development for the treatment of osteoarthritis knee pain.



"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 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."

Endo currently expects to launch the differentiated branded product in the United States in 2025.

Under the terms of the agreement, 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.

The upfront payment of \$30 million will be expensed in the second quarter as acquired in-process research and development. This expense was not reflected in Endo's second quarter 2022 financial guidance provided on May 5, 2022 as the transaction was signed after the date of the second quarter earnings release.

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 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 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](https://www.linkedin.com/company/endo).

About TLC

TLC 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 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, ophthalmology, and oncology.

Forward-Looking Statements

Certain information in this press release may be considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and any applicable Canadian securities legislation including, but not limited to, the statements by Messrs. Barry and Yeh and any statements related to the expansion of Endo's product portfolio or the development, approval, commercialization, manufacturing, marketing, sale or distribution of any products. Statements including words or phrases such as "believe," "expect," "anticipate," "intend," "estimate," "plan," "will," "may," "look forward," "intend," "future," "potential" or similar expressions are forward-looking statements. All forward-looking statements in this press release reflect Endo's current expectations of future events based on existing trends and information and represent Endo's judgment only as of the date of this press release. Actual results may differ materially and adversely from current expectations based on a number of factors affecting Endo's businesses, including, among other things, the following: the outcome of our strategic review, contingency planning and any potential restructuring; the timing, impact or results of any pending or future litigation, investigations, proceedings or claims, including opioid, tax and antitrust matters; actual or contingent liabilities; settlement discussions or negotiations; the impact of competition including loss of exclusivity and generic competition; our ability to satisfy judgments or settlements or to pursue appeals including bonding requirements; our ability to adjust to changing market conditions; our inability to maintain compliance with financial covenants and operating obligations which would expose us to potential events of default under our outstanding indebtedness; our ability to incur additional debt or refinance our outstanding indebtedness; a significant reduction in our short-term or long-term revenues which could cause us to be unable to fund our operations and liquidity needs; the effectiveness of advertising and other promotional campaigns; unfavorable publicity regarding the misuse of opioids; and our ability to develop our product pipeline and to continue to develop the market for products. The occurrence or possibility of any such result has caused us to engage, and may result in further engagement, in strategic reviews that ultimately may result in our pursuing one or more significant corporate transactions or other remedial measures, including on a preventative or proactive basis. Those remedial measures could include a potential corporate reorganization, restructuring or bankruptcy filing involving all or a portion of our business, asset sales or other divestitures, cost-saving initiatives, corporate realignments or strategic partnerships. Some of these measures could take significant time to implement and others may require judicial or other third-party approval. Any such actions may be complex, could entail significant costs and charges or could otherwise negatively impact shareholder value, and there can be no assurance that we will be able to accomplish any of these alternatives on terms acceptable to us, or at all, or that they will result in their intended benefits. Therefore, the reader is cautioned not to rely on any forward-looking statements. Endo expressly disclaims any intent or obligation to update these forward-looking statements, except as required to do so by law. Additional information concerning risk factors, including those referenced above, can be found in press releases issued by Endo, as well as Endo's public periodic filings with the U.S. Securities and Exchange Commission and with securities regulators in Canada, including the discussion under the heading "Risk Factors" in Endo's most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q or other filings with the U.S. Securities and Exchange Commission.

References:

1. 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.

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SOURCE Endo International plc

Endo International plc: Media: Heather Zoumas-Lubeski, (484) 216-6829, media.relations@endo.com; Investors: Laure Park, (845) 364-4862, relations.investor@endo.com