



TLC Receives Australian and Taiwan Approval to Initiate Phase I Clinical Trial of TLC19 Inhalable Liposomal Hydroxychloroquine for COVID-19

Dual government support in streamlined development of anti-COVID-19 therapy

SOUTH SAN FRANCISCO, CA and TAIPEI, Taiwan – October 7 , 2020 – TLC (Nasdaq: TLC, TWO: 4152), a clinical-stage specialty pharmaceutical company developing novel nanomedicines to target areas of unmet medical need, today announced the receipt of ethical and scientific approval from the Bellberry [Human Research Ethics Committee \(HREC\)](#) in Australia for the Company's Phase I clinical trial of [TLC19 Hydroxychloroquine Liposome Inhalation Suspension](#) for Coronavirus disease 2019 (COVID-19). The HREC is constituted in accordance with the requirements of the [National Health & Medical Research Council \(NHMRC\)](#), and reviews clinical trial proposals to ensure that they are ethically and scientifically acceptable and have been developed in accordance with relevant standards and guidelines. The approval comes following the acceptance of TLC's investigational new drug (IND) application with the Taiwan Food and Drug Administration (TFDA) yesterday.

"Taiwan has been widely recognized by the international community for successful measures taken in the battle against COVID-19. As a part of the government's 'Taiwan Can Help' initiative, TLC is committed to the speedy provision of a practical bridging strategy to fend off the spread of the virus until a safe and effective vaccine becomes widely available," said George Yeh, President of TLC. "We very much look forward to launching TLC19's Phase 1 trial with the support of experienced, high-quality partners in Taiwan as well as in Australia, which has an efficient and globally recognized regulatory environment with the bonus of government incentives and benefits and is a great place to conduct clinical trials for time-sensitive projects like TLC19. The receipt of this ethics approval is an important step in our clinical trial notification (CTN) application process."

The Phase I randomized, vehicle-controlled, blinded study will evaluate the safety, tolerability, and pharmacokinetics of single ascending doses of inhaled TLC19 in 30 healthy volunteers. Data from this trial will serve as a basis for subsequent clinical trials in patients with COVID-19.

Australia has a diverse participant recruitment pool, and the Australian government offers a financial rebate of 40% or more on clinical trial spending under the Research & Development tax incentive program.

About TLC19

TLC19 is liposomal suspension of hydroxychloroquine (HCQ) for inhalation. HCQ has shown potential in prophylaxis and/or treatment for COVID-19 in *in vitro* and preliminary clinical trial studies, but orally administered HCQ cannot reach therapeutic levels due to its dose-limiting toxicities. TLC19 utilizes ~1% of the highest oral HCQ



dose tested and delivers the drug directly to the airways and lungs, potentially avoiding systemic toxicities associated with oral HCQ while providing a sustained effective concentration at the primary site of infection. TLC19 is designed to be cost-effective, easily accessible and can be self-administered with a portable nebulizer.

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.

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. 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 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, 2019 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.

Contact

Dawn Chi
Corporate Communications
dawn@tlcbio.com