



## **TLC Announces Acceptance of Manuscript on Anti-COVID-19 Program by *Clinical and Translational Science Journal***

*Technology can be quickly translated and applied to other drugs for direct, extended release delivery to the lungs and is open for collaboration*

**SOUTH SAN FRANCISCO, CA and TAIPEI, Taiwan – November 3, 2020 – TLC** (Nasdaq: TLC, TWO: 4152), a clinical-stage specialty pharmaceutical company developing novel nanomedicines to target areas of unmet medical need, today announced that the manuscript describing how inhalable liposomal hydroxychloroquine (TLC19) may provide clinical benefit and serve as a potential treatment for COVID-19 has been peer-reviewed and accepted by *Clinical and Translational Science (CTS)* journal. *CTS* highlights original research that helps bridge laboratory discoveries with the diagnosis and treatment of human disease and is an official journal of the American Society of Clinical Pharmacology and Therapeutics (ASCPT).

“We are honored to be sharing this peer-reviewed manuscript in an internationally acclaimed journal,” said George Yeh, President of TLC. “CTS has a collection of clinical pharmacology research from various potential treatments such as remdesivir, favipiravir, and lopinavir/ritonavir. Acknowledgment of our work by CTS further fortifies the soundness of our strategy of preferential delivery to the lungs. In these unprecedented times, we wish to do all that we can to help, and we openly welcome partnerships to re-formulate drugs with high potency against SARS-CoV-2 virus but low bioavailability utilizing our proprietary inhalable liposomal formulation in order to create more potential remedies to address this global pandemic.”

The accepted manuscript titled “A Strategy to Treat COVID-19 Disease with Targeted Delivery of Inhalable Liposomal Hydroxychloroquine: A Pre-clinical Pharmacokinetic Study” can be found on the ASCPT website using the following link: <https://ascpt.onlinelibrary.wiley.com/doi/epdf/10.1111/cts.12923>. The research, which was previously available as pre-print on bioRxiv.org, is a collaborative work by TLC in conjunction with key opinion leader in respiratory therapies – Dr. Huey-Dong Wu, Senior Pulmonologist at the Department of Integrated Diagnostics and Therapeutics at National Taiwan University Hospital – and the leading authority in infectious diseases – Dr. Yee-Chun Chen, Professor of Medicine at National Taiwan University Hospital and College of Medicine, Investigator of the National Institute of Infectious Diseases and Vaccinology, National Health Research Institutes of Taiwan, and Board Member and Vice President of the International Society for Human and Animal Mycology (ISHAM).

“There is an unmet medical need for a therapy that is accessible and affordable for everyone affected by the COVID-19 pandemic,” said Dr. Chen. “Altering the route of administration of hydroxychloroquine from oral to inhalation substantially increases exposure in the airways and lungs while decreasing exposure in the system, and a liposomal formulation allows sustained residence of the drug in the lungs. I am happy to see these principles reflected in the results of this preclinical study and look forward



to seeing more encouraging data from the clinical trials.”

A Phase I randomized, vehicle-controlled, blinded study evaluating the safety, tolerability, and pharmacokinetics of inhaled TLC19 in healthy volunteers is ongoing.

### **About TLC19**

TLC19 is a 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.

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