



TLC Enrolls First Subject in Phase I Clinical Trial of Inhalable Anti-COVID-19 Program (TLC19)

SOUTH SAN FRANCISCO, CA and TAIPEI, Taiwan – October 14, 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 first subject has been enrolled in the Phase I clinical trial of **TLC19** for treatment or prophylaxis of Coronavirus disease 2019 (COVID-19).

TLC19 is a proprietary liposomal formulation of a small amount of hydroxychloroquine (HCQ) for inhalation. A [paper by Kavanagh, Oisín et al](#) suggests that inhaled HCQ may improve efficacy and reduce harm in the treatment of COVID-19, and liposomal formulations have long been shown to possess the advantages of efficient drug delivery directly to the disease site and achieving sustained release to prolong drug residence time. In preclinical studies, TLC19 demonstrated 30-fold exposure in the lungs while achieving lower blood and heart exposure than oral HCQ and unformulated HCQ. Thus, TLC19 can potentially inhibit the first-line entry and replication of SARS-CoV-2 in the upper respiratory tract and lungs, as well as preventing its subsequent neuro-invasion to the brain.

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 volunteer subjects. Three dose levels – 4mg, 8mg, and 12mg – will be assessed in sequential cohorts. Within each cohort, approximately 10 evaluable subjects will be enrolled and randomized in a ratio of 8:2, with 8 subjects receiving TLC19 and 2 subjects receiving a TLC19 vehicle, which is the same liposomal formulation but without the active pharmaceutical ingredient of hydroxychloroquine. Study medication is administered through inhalation via a commercially available portable vibrating mesh nebulizer, and all subjects will be followed up for 4 weeks.

“The prompt commencement of subject enrollment is a testament of our dedication to accelerate the TLC19 program as quickly as possible,” said George Yeh, President of TLC. “Within the last 24 hours, two late-stage COVID-19 clinical trials in the United States – a vaccine and a monoclonal antibody – have been suspended, making our mission to provide a means of defense against the deadly virus more important than ever. Along with our clinical progress in Australia and Taiwan, we are also making good speed on the GMP manufacturing side, preparing for large-scale commercial production of TLC19 in Taiwan and potentially in the United States.”

The [International Society for Aerosols in Medicine \(ISAM\)](#) issued a [statement](#) imploring regulatory authorities to use prior, documented safety data already in their possession to expedite the development of “repurposed” out-of-patent drugs for the inhaled route of administration during COVID-19, as the doses required to achieve high lung concentrations are typically much lower than their daily doses by other routes. As TLC19 is a repurposed, inhaled version of the off-patent malaria drug HCQ, physiologically based pharmacokinetic modeling from the Phase I pharmacokinetic



results could be leveraged to rapidly enable dosing in subsequent trials of patients with COVID-19, which TLC plans to conduct in areas impacted the most by the pandemic.

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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