Lipella Pharmaceuticals Announces Completion of First Cohort in Phase 2a Trial of LP-310 for Oral Lichen Planus, Advancing to Next Dose Group

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PITTSBURGH, Nov. 21, 2024 (GLOBE NEWSWIRE) -- Lipella Pharmaceuticals Inc. (Nasdaq: LIPO) ("Lipella" or the "Company"), a clinical-stage biotechnology company focused on innovative therapies for serious diseases with significant unmet needs, today announced the completion of dosing for the first cohort in its multi-center Phase 2a clinical trial of LP-310, a liposomal-tacrolimus oral rinse being developed for the treatment of Oral Lichen Planus (OLP).

In this first cohort, eight participants received a dose of 0.25 mg LP-310, with promising initial results. No product-related serious adverse events were reported. Pharmacokinetic data demonstrated that whole blood tacrolimus levels in all patients were either undetectable or minimal, highlighting LP-310's potential to deliver localized therapeutic effects while minimizing systemic exposure. Additionally, all patients tolerated LP-310 without significant adverse reactions.

Janet Okonski, Director of Clinical Operations at Lipella Pharmaceuticals, noted feedback from the study site, stating, "The tolerability observed in this initial cohort is a promising indicator. Oral Lichen Planus severely affects patient quality of life, and an effective, well-tolerated treatment is desperately needed. It's encouraging to see this kind of response at an early stage."

Following a successful internal safety evaluation of the first dose cohort, the trial has received approval to advance to the next stage of the trial, which will evaluate a higher dose of 0.5 mg of LP-310.

"We are proud of this milestone and are grateful to our investigators and study staff for their dedication and hard work," said Dr. Michael Chancellor, Chief Medical Officer of Lipella Pharmaceuticals. "Our commitment to developing a safe and effective therapy for Oral Lichen Planus patients remains steadfast as we activate additional sites and begin enrolling the next dose cohort. The pace of our progress has been promising, and we are on track to deliver top-line data by year-end and complete the trial by mid-2025."

Oral Lichen Planus (OLP) is a chronic inflammatory condition that affects the mucous membranes inside the mouth, which can cause pain and make eating, drinking and even speaking uncomfortable. Characterized by symptoms such as burning pain, white patches, swollen tissue, and open sores, OLP impacts approximately 6 million Americans and currently has no FDA-approved therapies.

About the Study

The Oral Lichen Planus Clinical Trial is a multicenter, dose-ranging study involving adult male and female subjects (18 years and older) with symptomatic OLP. This study will evaluate the safety, tolerability and efficacy of LP-10 at doses of 0.25 mg, 0.5 mg and 1.0 mg of tacrolimus. Seven sites across the U.S. are now active and recruiting participants for the trial. For more information, please visit https://clinicaltrials.gov/study/NCT06233591.

The clinical trial is expected to conclude by mid-2025, with top-line data anticipated by year-end 2024. The early results indicate the potential of LP-310 as a breakthrough treatment for OLP, a condition that severely impacts patients' quality of life.

About Lipella Pharmaceuticals Inc.
Lipella Pharmaceuticals is a clinical-stage biotechnology company focused on developing new drugs by reformulating active agents in existing generic drugs and optimizing these reformulations for new applications. Lipella targets diseases with significant unmet needs, where no approved drug therapies currently exist. The company completed its initial public offering in 2022.

Forward-Looking Statements
This press release includes certain “forward-looking statements.” All statements, other than statements of historical fact, included in this press release regarding, among other things, our strategy, future operations, financial position, prospects, pipeline and opportunities, sources of growth, successful implementation of our proprietary technology, plans and objectives are forward-looking statements. Forward-looking statements can be identified by words such as “may,” “will,” “could,” “continue,” “would,” “should,” “potential,” “target,” “goal,” “anticipates,” “intends,” “plans,” “seeks,” “believes,” “estimates,” “predicts,” “expects,” “projects” and similar references to future periods. Forward-looking statements are based on our current expectations and assumptions regarding future events and financial trends that we believe may affect among other things, our financial condition, results of operations, business strategy, short- and long-term business operations and objectives, and financial needs. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. Our actual results may differ materially from those contemplated by the forward-looking statements. We caution you, therefore, against relying on any of these forward-looking statements. They are neither statements of historical fact nor guarantees or assurances of future performance. There are risks, uncertainties and other factors, both known and unknown, that could cause actual results to differ materially from those in the forward-looking statements which include, but are not limited to, regional, national or global political, economic, business, competitive, market and regulatory conditions, and other factors. Any forward-looking statement made by us is based upon the reasonable judgment of our management at the time such statement is made and speaks only as of the date on which it is made. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by applicable law. Nothing contained herein is, or shall be relied upon as, a promise or representation as to the past or future. In addition, the information contained in this press release is as of the date hereof, and the Company has no obligation to update such information, including in the event that such information becomes inaccurate. You should not construe the contents of this press release as legal, tax and financial advisors as to legal and related matters concerning the matters described herein.