Lipella Pharmaceuticals Reports Encouraging Early Tolerability Results in Phase 2a Trial of LP-310 for Oral Lichen Planus

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PITTSBURGH, Sept. 24, 2024 (GLOBE NEWSWIRE) -- Lipella Pharmaceuticals Inc. (Nasdaq: LIPO) ("Lipella" or the "Company"), a clinical-stage biotechnology company focused on addressing serious diseases with significant unmet needs, today announced an update on its ongoing multi-center Phase 2a clinical trial evaluating LP-310 for the treatment of Oral Lichen Planus (OLP). The Company reported that three participants have completed the four-week treatment with LP-310, an oral rinse, with encouraging findings: The treatment was well tolerated and had no unpleasant taste.

Dr. Michael Chancellor, Chief Medical Officer of Lipella Pharmaceuticals, commented, "Oral Lichen Planus is a highly disruptive condition that significantly impacts patients' daily lives. Given the severity of symptoms, tolerability is critical. Symptomatic side effects from current treatments often lead to frequent dose interruptions or delays, which can further complicate disease management. The fact that LP-310 has been well tolerated so far, without unpleasant taste, is very encouraging. We look forward to gathering more data on the safety side as we continue this pivotal trial."

LP-310 is a proprietary liposomal-tacrolimus formulation derived from Lipella's lead candidate, LP-10, which was initially developed for hemorrhagic cystitis. LP-310 targets the underlying causes of OLP and aims to provide a more effective alternative to the currently available palliative treatments by delivering a concentrated therapeutic effect directly in the oral cavity while minimizing systemic toxicity. Currently, there are no FDA-approved pharmacotherapies for Oral Lichen Planus, and LP-310 is the only topical treatment in development for OLP.

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. Five 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

Lipella is a clinical-stage biotechnology company focused on developing new drugs by reformulating the active agents in existing generic drugs and optimizing these reformulations for new applications. Additionally, Lipella maintains a therapeutic focus on diseases with significant, unaddressed morbidity and mortality where no approved drug therapy currently exists. Lipella completed its initial public offering in December 2022. For more information, please visit www.lipella.com or LinkedIn

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.