

Lipella Pharmaceuticals Doses First Two Patients in Phase 2a Oral Lichen Planus Clinical Trial

Top Line Data Expected Year-End 2024

August 12, 2024 05:00 ET

PITTSBURGH, Aug. 12, 2024 (GLOBE NEWSWIRE) -- Lipella Pharmaceuticals Inc. (Nasdaq: LIPO) (“Lipella,” “our,” “us,” “we” or the “Company”), a clinical-stage biotechnology company addressing serious diseases with significant unmet need, today announces the dosing of the first two patients with LP-310 in its Phase 2a clinical trial in Oral Lichen Planus (OLP) patients.

Lipella’s Phase 2a trial is a multicenter, dose-ranging study involving adult male and female subjects experiencing symptomatic Oral Lichen Planus, a chronic inflammatory condition that affects mucous membranes in the mouth and causes burning and pain as well as white patches, swollen tissue or open sores. OLP affects about 6 million Americans and currently has no FDA-approved therapies.

LP-310 is a novel liposomal-tacrolimus oral rinse based on the company's lead candidate LP-10, which is also being evaluated for hemorrhagic cystitis. This study is expected to conclude in mid-2025. Lipella Pharmaceuticals anticipates reporting top-line data from the study by the end of 2024.

Dr. Michael Chancellor, Chief Medical Officer of Lipella, stated, “Oral Lichen Planus poses significant challenges, including severe pain, risk of infections, scarring and potential malignant transformation, and the psychological burden on patients further exacerbates the condition. Current treatments are largely palliative. Our goal with LP-310 is to address the underlying mechanisms of OLP, aiming for substantial symptom relief and reduced risk of complications, and to deliver the first approved drug treatment for Oral Lichen Planus to this underserved patient population.”

Dr. Michael Brennan, Chairman of the Department of Oral Medicine/Oral & Maxillofacial Surgery and principal investigator at Atrium Health Carolinas Medical Center, added, “The initiation of this trial is a crucial step towards filling the substantial gap in effective treatments for Oral Lichen Planus. There is a clear and pressing need for FDA-approved therapies, and patients are eager for new options.”

About Oral Lichen Planus

Oral Lichen Planus (OLP) is a serious and debilitating condition characterized by oral mucosal lesions. It affects millions of individuals worldwide and presents significant challenges in terms of management and treatment. Current therapeutic options are limited, underscoring the critical need for innovative approaches like LP-310 in addressing this unmet medical need.

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.

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.