Lipella Pharmaceuticals Initiates Phase 2a Trial for LP-310 in Oral Lichen Planus, Enrolls First Patients

Top Line Data Expected Year-End 2024

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PITTSBURGH, July 29, 2024 (GLOBE NEWSWIRE) -- Lipella Pharmaceuticals Inc. (Nasdaq: LIPO) (“Lipella” or the “Company”), a clinical-stage biotechnology company addressing serious diseases with significant unmet need, today announced the enrollment of the first patients in its multi-center Phase 2a clinical trial evaluating LP-310 for the treatment of Oral Lichen Planus (OLP). This chronic inflammatory condition, which affects over 6 million Americans, is characterized by mouth mucous membrane inflammation, pain, and ulceration, and lacks FDA-approved treatments.

Lipella's Phase 2a trial is a multi-center, dose-ranging study of LP-310, a proprietary liposomal-tacrolimus oral rinse formulation of the company’s lead candidate LP-10 for hemorrhagic cystitis. The trial has enrolled its first patients across multiple research sites nationwide, spanning from Philadelphia to San Francisco, and is actively screening additional subjects with symptomatic Oral Lichen Planus.

Dr. Jonathan Kaufman, CEO of Lipella Pharmaceuticals, commented, "We are very pleased with the rapid pace of site activation, and the enrollment of our initial patients marks a pivotal milestone for both the company and the patient community suffering from this debilitating condition. This achievement reinforces our mission to redefine treatment paradigms for Oral Lichen Planus. With LP-310’s innovative approach to targeting disease mechanisms, we are excited about the potential to deliver a transformative therapy, alleviating symptoms and improving patient outcomes significantly."

LP-310 is designed to address the underlying causes of OLP, offering a promising alternative to current palliative treatments and delivering local concentration in the oral cavity, aiming to minimize systemic toxicity. The trial is anticipated to conclude by mid-2025, with top-line data expected year-end 2024.

Dr. Michael Chancellor, Chief Medical Officer of Lipella added, “We have heard the urgency for new effective OLP therapies from patients, clinicians and advocacy groups. OLP not only induces debilitating physical symptoms but also poses risks of serious complications. LP-310's potential to mitigate these challenges represents a significant advancement in therapeutic 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.