

Lipella Pharmaceuticals Completes Enrollment in Phase 2a Trial of LP-310 for Oral Lichen Planus

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Topline Results Expected Q2 2025

PITTSBURGH, April 08, 2025 (GLOBE NEWSWIRE) -- Lipella Pharmaceuticals Inc. (Nasdaq: LIPO) (“Lipella” or the “Company”), a clinical-stage biotechnology company focused on developing innovative therapies for unmet medical needs, today announced the completion of enrollment in its Phase 2a multicenter, dose-ranging trial evaluating LP-310, a liposomal tacrolimus oral rinse for the treatment of oral lichen planus (OLP). The Phase 2a trial has now fully enrolled participants across all three dose cohorts (0.25 mg, 0.50 mg and 1.0 mg of tacrolimus) at seven U.S. study sites. Topline results from the final cohort (1.0 mg) remain on track for the second quarter of 2025 and will represent the most comprehensive clinical dataset to date for LP-310.

“The completion of enrollment in our Phase 2a trial marks an important step in advancing a non-steroidal, locally delivered treatment for oral lichen planus, an underserved condition with no FDA-approved therapies,” said Dr. Michael Chancellor, Co-Founder and Chief Medical Officer of Lipella Pharmaceuticals. “We have already observed encouraging safety and efficacy signals in the first two dose cohorts, including clinically meaningful reductions in pain, ulceration and inflammation. With the final cohort now fully enrolled, we look forward to reporting topline results in the near term and believe this dataset will be critical in informing next steps for development and broader clinical strategy.”

About the Phase 2a Trial

The Phase 2a trial is a multicenter, dose-ranging study designed to evaluate the safety, tolerability and preliminary efficacy of LP-310 in adult patients with symptomatic oral lichen planus. The trial consists of three dose levels (0.25 mg, 0.50 mg and 1.0 mg), administered as a twice-daily 10-milliliter oral rinse over four weeks. The study’s primary objectives include assessing LP-310’s safety profile and pharmacokinetics, while secondary endpoints evaluate its impact on pain, inflammation and oral ulceration using patient-reported and investigator-measured scoring systems.

About Oral Lichen Planus (OLP)

OLP is a chronic, T-cell-mediated autoimmune disorder affecting the oral mucosa, often causing painful erosions, inflammation and ulcerative lesions. The condition impacts an estimated 6 million Americans, and there are currently no FDA-approved treatments available.

Next Steps in Development

With enrollment complete, Lipella remains on track to:

- Report topline results from the 1.0 mg cohort in the first half of 2025
- Submit an Investigational New Drug (IND) application for a Phase 2b trial in late 2025

- Explore potential regulatory designations, including Breakthrough Therapy designation

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" which are not historical facts, within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, included in this press release regarding, among other things, our strategy, future operations, financial position, prospects, clinical trials, regulatory approvals, 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, market and other conditions, 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, the current clinical trial results for LP-310 and our other products general capital market risks, our ability to regain and maintain compliance with the listing standards of The Nasdaq Stock Market LLC, regional, national or global political, economic, business, competitive, market and regulatory conditions, our current liquidity position and the need to obtain additional financing to support ongoing operations, and other risks as more fully described in our filings with the U.S. Securities and Exchange Commission. 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 or investment advice and should consult with your own advisors as to the matters described herein, as applicable.