Lipella Pharmaceuticals Reports Positive Topline Phase 2a Results for LP-310 in the Treatment of Oral Lichen Planus

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LP-310 Treatment Demonstrates Clinically Meaningful Reductions in Pain, Ulceration, and Inflammation Across All Key Metrics

Findings Highlight Favorable Safety Profile and Tolerability of Twice-Daily Oral Rinse

Multicenter Phase 2a Trial Advancing to Higher Treatment Dose with Recruitment Expected to Conclude the First Half of 2025

Lipella Leadership to Present Findings at BIO CEO & Investor Conference on Tuesday, February 11, 2025, at 2:30 p.m. EST

PITTSBURGH, Feb. 11, 2025 (GLOBE NEWSWIRE) -- Lipella Pharmaceuticals Inc. (Nasdaq: LIPO) ("Lipella," "our," "us," or the "Company"), a clinical-stage biotechnology company addressing serious diseases with significant unmet needs, today shared topline analysis of its Phase 2a multicenter dose-ranging trial examining LP-310, a liposomal-tacrolimus oral rinse formulation of LP-10 being developed to treat oral lichen planus ("OLP").

LP-310 demonstrated a strong safety profile, with no product-related serious adverse events (SAEs) and no patient dropouts. The trial showed statistically significant improvements across multiple patient-reported and investigator-measured efficacy endpoints at weeks 1, 4, and 6. LP-310 is the only oral rinse topical treatment currently in development for OLP.

Lipella Pharmaceuticals' management will provide an overview of the Company and present results from the study during the BIO CEO & Investor Conference at The New York Marriott Marquis in New York City on Tuesday, Feb. 11, 2025, at 2:30 p.m. EST in the Plymouth Room.

Affecting about 6 million Americans, OLP is a chronic inflammatory condition that targets mucous membranes in 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 has no FDA-approved therapies.

"OLP represents a significant unmet need, and these remarkable results are highly encouraging, underscoring the meaningful value LP-310 can bring to both patients and the broader healthcare system," added Jonathan Kaufman, Co-Founder and CEO of Lipella Pharmaceuticals. "With a chronic condition like OLP, delivering a targeted, effective treatment that overcomes the challenges of current options is vital. We are thrilled to advance its development and unlock its full potential."

In the study's first cohort, eight participants received a twice-daily dose of 0.25 mg of LP-310. Follow-up visits occurred at one and four weeks as well as two weeks post-treatment. The trial showed significant improvements across multiple efficacy endpoints while suggesting the safety and tolerability of LP-10 in adult patients with symptomatic OLP at the

0.25 mg/10 mL dose. The trial, which is active across seven U.S. sites, has progressed to the next higher dose cohort of 0.5 mg/10 mL.

Topline Findings:

- **Investigator Global Assessment (IGA):** Improved from 3.50 ± 0.19 at baseline to 2.75 ± 0.31 at week 1 (p=0.031), 1.75 ± 0.45 at week 4 (p=0.008), and 2.80 ± 0.37 at week 6 (p=0.125).
- **Reticulation, Erythema, and Ulceration (REU) Score:** Reduced from 27.75 ± 2.71 at baseline to 17.56 ± 2.51 at week 1 (p=0.004), 12.69 ± 3.06 at week 4 (p=0.004), and 19.60 ± 4.31 at week 6 (p=0.031).
- **Oral Lichen Planus Symptom Severity Measure (OLPSSM):** Decreased from 15.38 ± 2.20 at baseline to 10.13 ± 2.34 at week 1 (p=0.035), 5.00 ± 2.28 at week 4 (p=0.004), and 8.60 ± 4.06 at week 6 (p=0.031).
- **Pain Numerical Rating Scale (NRS):** Improved from 6.63 ± 0.80 at baseline to 4.38 ± 0.96 at week 1 (p=0.004), 2.38 ± 1.15 at week 4 (p=0.004), and 3.60 ± 1.63 at week 6 (p=0.031).
- **Global Response Assessment (GRA):** Significant improvement was observed at week 4 (p=0.031).

“The statistically significant reductions in pain, ulceration, and inflammation observed in this trial provide strong grounds for the scientific validation of LP-310’s efficacy,” said Dr. Michael Chancellor, Co-Founder and Chief Medical Officer of Lipella Pharmaceuticals. “These results, combined with the treatment’s favorable safety profile, highlight the potential of LP-310 to deliver a highly targeted and tolerable therapy for OLP. We are deeply grateful to the patients and investigators for their contributions to this critical study and inspired by the marked improvements we’ve seen in patients’ lives. We look forward to advancing the trial to the next dose cohort and expanding recruitment across seven active U.S. sites as we continue to build on these promising findings.”

Safety and Tolerability

LP-310 was well tolerated with no product-related serious adverse events reported. All patients adhered to the twice-daily 10 mL rinse regimen, with no dropouts during the study. Pharmacokinetic analysis showed that tacrolimus blood levels were undetectable or minimal in all patients, underscoring LP-310’s potential to deliver localized benefits without systemic toxicity.

Next Steps in Development

Lipella continues to recruit for the trial, with plans to activate additional sites and complete the trial by mid-2025. The company is preparing for key milestones, including the submission of a Phase 2b clinical trial investigational new drug application in the second half of 2025 and a Breakthrough Therapy designation request to the FDA during the same period.

About LP-310

LP-310 is an innovative oral rinse formulation of LP-10 (tacrolimus), developed to address

OLP. Designed to provide localized therapeutic effects while minimizing systemic exposure, LP-310 offers a promising new approach to managing this painful and often debilitating condition.

A Phase 2a multicenter, dose-ranging clinical trial is currently underway to evaluate the safety, tolerability and efficacy of LP-310 in adult participants with symptomatic OLP. The trial includes three dose levels (0.25 mg, 0.5 mg, and 1.0 mg of tacrolimus) and is being conducted across seven active U.S. sites, which are now recruiting participants. The study has reported topline data from its first cohort, with the second cohort currently dosing and topline data expected in the first half of 2025.

For more information about the study or to participate,
visit https://clinicaltrials.gov/study/NCT06233591.

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.