Lipella Pharmaceuticals to Present Phase 2a Data for LP-310 in Oral Lichen Planus at 2025 AAOM/EAOM International Meeting

May 15, 2025 09:00 ET

Statistically significant safety and efficacy data from 0.25 mg and 0.50 mg cohorts to be presented

Presentation scheduled for Thursday, May 15, 2025, at 11:36 a.m. PT

PITTSBURGH, May 15, 2025 (GLOBE NEWSWIRE) -- Lipella Pharmaceuticals Inc. (Nasdaq: LIPO) ("Lipella," "we," "our," or the "Company"), a clinical-stage biotechnology company focused on developing therapies for diseases with significant unmet needs, today announced that topline data from the first two dose cohorts of its ongoing Phase 2a trial of LP-310 (liposomal tacrolimus oral rinse) for the treatment of Oral Lichen Planus (OLP) will be presented at the 2025 joint international meeting of the American Academy of Oral Medicine (AAOM) and the European Association of Oral Medicine (EAOM) in Las Vegas.

Presentation Details

- **Title:** *Liposomal Tacrolimus (LP-310) Oral Rinse for the Treatment of Oral Lichen Planus: Topline Analysis of a Phase 2a Multicenter Dose-Ranging Trial*
- **Presenter:** Dr. Alessandro Villa, Chief of Oral Medicine, Oral Oncology, and Dentistry, Miami Cancer Institute
- **Date & Time:** Thursday, May 15, 2025, at 11:36 a.m. PT
- **Location:** 2025 AAOM/EAOM International Meeting, Las Vegas, NV

Presentation Highlights:
The data to be presented includes safety and efficacy findings from the 0.25 mg and 0.50 mg dose cohorts of LP-310, administered once daily over four weeks in adults with symptomatic OLP. The primary endpoint was assessed at Week 4, with follow-up at Week 6.

Treatment at the 0.50 mg dose demonstrated statistically significant improvements in multiple endpoints:

- **Investigator Global Assessment (IGA):** Improved from 3.42 at baseline to 1.71 at Week 4 (p=0.007)
- **REU Score (Reticulation, Erythema, Ulceration):** Reduced from 26.91 to 11.88 at Week 4 (p=0.003)
- **Oral Lichen Planus Symptom Severity Measure (OLPSSM):** Dropped from 14.92 to 4.88 at Week 4 (p=0.003)
- **Pain Numerical Rating Scale (NRS):** Improved from 6.42 to 2.25 at Week 4 (p=0.003)

Visible lesion resolution was observed during treatment. A return toward baseline following cessation of dosing supports localized on-treatment activity.

LP-310 was well tolerated, with no treatment-related serious adverse events (SAEs), no patient discontinuations, and no detectable systemic tacrolimus levels. All participants adhered to the once-daily regimen.

“The positive data from the 0.50 mg cohort showed consistent improvements across patient-reported and clinician-assessed measures. We’re encouraged by the reductions in pain, inflammation, and ulceration,” said Dr. Michael Chancellor, Chief Medical Officer and Co-Founder of Lipella Pharmaceuticals. “These findings support LP-310’s potential as a localized, non-steroidal treatment for Oral Lichen Planus. We look forward to sharing final topline data from the fully enrolled trial in the second quarter of 2025.”

About the Study

The Phase 2a trial is a multicenter, dose-ranging study evaluating the safety, tolerability, and efficacy of LP-310 in adults (18 years and older) with symptomatic Oral Lichen Planus. Three dose levels—0.25 mg, 0.5 mg, and 1.0 mg—are being assessed. LP-310 was administered once daily for four weeks. The primary endpoint was measured at Week 4, with follow-up at Week 6 to assess durability of response.

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. Learn more at lipella.com and follow us on X and 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, clinical trials, including the statistically significant safety and efficacy data presented above for LP-310, 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, risks related to the current clinical trial for LP-310, general capital market risks, regional, national or global political, economic, business, competitive, market and regulatory conditions, and other risks that may be included in the periodic reports and other filings that the Company files from time to time 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 and financial advisors as to legal and related matters concerning the matters described herein.