

Lipella Pharmaceuticals Abstract on Oral Lichen Planus Treatment Accepted for Podium Presentation at 2025 AAOM/EAOM International Meeting Conference on “Global Transformation in Oral Medicine”

April 23, 2025 08:30 ET

Joint meeting to be held in Las Vegas, May 14-17

Presentation will be delivered by Dr. Alessandro Villa of Miami Cancer Institute

Topline study results demonstrate clinically meaningful improvements in OLP

Visible lesion resolution during treatment; return toward baseline post-dosing supports localized activity

PITTSBURGH, April 23, 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 its abstract on LP-10 for the treatment of Oral Lichen Planus (OLP) has been accepted for podium presentation at the 2025 joint international meeting of the American Academy of Oral Medicine (AAOM) and European Association of Oral Medicine (EAOM). The meeting will take place May 14–17 in Las Vegas. The presentation will be delivered by Dr. Alessandro Villa, Chief of Oral Medicine, Oral Oncology and Dentistry, and Professor at Herbert Wertheim College of Medicine, Miami Cancer Institute, on May 15.

The abstract, titled "Liposomal Tacrolimus (LP-10) Oral Rinse for the Treatment of Oral Lichen Planus: Topline Analysis of a Phase 2a Multicenter Dose-Ranging Trial," presents data from an ongoing trial evaluating LP-10, a liposomal formulation of tacrolimus, in patients with symptomatic OLP—a chronic inflammatory condition of the oral mucosa that can cause pain, white patches, swelling, and ulcerations. The oral rinse has demonstrated good tolerability and produced clinically meaningful improvements.

“As the global oral medicine community gathers this spring, we’re proud to present promising new data toward the goal of providing a safe and effective treatment for Oral Lichen Planus,” said Jonathan Kaufman, CEO and co-founder of Lipella. “Our topline results show significant improvement after just four weeks of treatment. This is a meaningful step forward for a patient population in need of recognition, support, and therapeutic options. We look forward to sharing final topline results from the fully enrolled trial, which are expected in the second quarter of 2025.”

“We observed statistically significant improvements across clinical measures, along with visible reductions in inflammation and resolution of ulcerative lesions in some patients,” said Dr. Michael Chancellor, Chief Medical Officer and Co-Founder of Lipella. “These effects were most evident at the end of the treatment period, supporting the clinical relevance of LP-10’s localized activity. Taken together, the data highlight LP-10’s potential as a non-steroidal therapeutic option for a chronic condition with no FDA-approved treatments.”

About the Study

The Oral Lichen Planus Phase 2a trial is a multicenter, dose-ranging study evaluating the

safety, tolerability, and efficacy of LP-10 oral rinse in adults (18 years and older) with symptomatic OLP. Three dose levels of tacrolimus—0.25 mg, 0.5 mg, and 1.0 mg—are being assessed. According to Lipella’s Chief Medical Officer Dr. Michael Chancellor, topline findings from the 0.5 mg cohort demonstrated statistically significant and clinically meaningful improvement ($p < 0.05$) at the primary endpoint, with all outcome measures showing significance at Week 4. A gradual decline in effect was observed by Week 6, two weeks after treatment ended. Investigators also noted visible improvement in oral lesions, including resolution of ulcerations in some patients. A gradual decline in effect was observed by Week 6, two weeks after treatment ended, suggesting strong on-treatment activity with a return toward baseline once dosing ceased.

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, 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 effective application of the use of proceeds from the private placement, general capital market risks, 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.