Lipella Pharmaceuticals Granted FDA Approval for Expanded Access Program for LP-310 in Oral Lichen Planus

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PITTSBURGH, Feb. 06, 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 that the U.S. Food and Drug Administration (FDA) has granted approval for an Expanded Access Program (EAP) for LP-310, an oral rinse formulation designed to treat oral lichen planus (OLP).

LP-310 is an innovative, localized therapy formulated to provide targeted relief for OLP patients while minimizing systemic exposure. Oral lichen planus is a chronic inflammatory condition affecting the mucous membranes inside the mouth, often causing burning pain, white patches, swollen tissue and open sores. The condition impacts approximately 6 million Americans and currently has no FDA-approved therapies.

Expanded Access Programs allow patients who have unmet medical needs with serious or life-threatening conditions to access treatments outside of a clinical trial that are not yet approved by the FDA.

"Receiving FDA approval for expanded use of LP-310 represents a key milestone in our mission to address the significant unmet need in oral lichen planus treatment," said Michael Chancellor, Co-Founder and Chief Medical Officer of Lipella Pharmaceuticals. "We are pleased to make LP-310 available to patients beyond our Phase 2a clinical trial through this expanded access program. With no approved therapies currently available, this approval strengthens our commitment to advancing LP-310 as a potential solution for patients living with this painful and often debilitating condition."

The FDA's approval for expanded use reinforces LP-310's potential as a new therapeutic option for OLP and supports ongoing clinical development efforts.

About LP-310
LP-310 is an oral rinse formulation of LP-10 (tacrolimus) developed to target inflammation and immune response in OLP patients. Designed for localized therapeutic effects, LP-310 minimizes systemic exposure, reducing the risks associated with long-term steroid use. 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.

About Lipella Pharmaceuticals Inc.
Lipella Pharmaceuticals is a clinical-stage biotechnology company focused on developing innovative therapies by reformulating active agents in existing generic drugs. Lipella targets diseases with significant unmet needs, where no approved treatments currently exist.

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.