

Lipella Pharmaceuticals Marks Successful First Year with Strategic Progress and Key Milestones Accomplished

Lipella Granted Two Orphan Drug Designations by FDA

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PITTSBURGH, Dec. 20, 2023 (GLOBE NEWSWIRE) -- Lipella Pharmaceuticals Inc., (Nasdaq: LIPO) ("Lipella," "our," "us" or the "Company"), a pioneering, clinical-stage pharmaceutical company, celebrates its first anniversary as a publicly traded entity. Based in Pittsburgh, PA, the Company has made substantial strides over the past year, achieving critical milestones and advancing its pipeline with three clinical indications and two orphan drug designations granted.

A highlight of the year includes the successful completion of a Type C meeting with the U.S. Food and Drug Administration (FDA) focused on the clinical program for LP-10, Lipella's leading drug candidate for the treatment of hemorrhagic cystitis (HC). Jonathan Kaufman, CEO of Lipella, expressed his satisfaction with the meeting's outcome, noting, "The FDA's feedback from our recent Type C meeting gives us a clear path forward into 2024. Our planned Phase-2b trial for LP-10 will involve 36 subjects in a double-blind, placebo-controlled study, focusing on the treatment's impact on gross hematuria."

Further bolstering its portfolio, Lipella has secured FDA approval for its Investigational New Drug (IND) application for a Phase 2a multicenter trial of an oral rinse formulation of LP-310, targeting Oral Lichen Planus (OLP). With central Institutional Review Board (IRB) approval in hand, the Company is in the process of selecting study sites for this trial.

Additionally, Lipella's LP-310 has been granted orphan drug designation for the treatment of oral graft-versus-host disease (GVHD) with tacrolimus. The Company is poised to submit a Phase 2a IND for this indication in the first quarter of 2024.

Reflecting on the Company's journey, Dr. Michael Chancellor, Lipella's Chief Medical Officer, remarked, "Our first year as a public company, especially during challenging market conditions, has been remarkable. Heading into 2024, we are enthusiastic about advancing our assets through clinical trials, bolstered by two orphan designations."

As Lipella Pharmaceuticals steps into another year of innovation and growth, it remains committed to developing groundbreaking treatments that address critical healthcare needs.

About LP-10 and LP-310

LP-10 is a liposomal tacrolimus formulation for intravesical administration to treat hemorrhagic cystitis (HC). LP-10 has been evaluated in a multi-center Phase 2a dose escalation trial of 13 subjects with moderate to severe refractory HC. Positive top line results demonstrated safety and efficacy, short duration of systemic uptake of LP-10, and a dose response including decreased hematuria, decreased cystoscopic bleeding and ulceration sites, and improved urinary symptoms in patients. Lipella has been granted Orphan Disease Designation by the FDA for LP-10 in the treatment of moderate to severe hemorrhagic cystitis. LP-310 liposomal tacrolimus is a proprietary oral rinse formulation of

Lipella's lead drug candidate, LP-10, for the indications of OLP and oral GVHD. Lipella has been granted orphan drug designation by the FDA for LP-310 in the treatment of GVHD.

About Hemorrhagic Cystitis

Hemorrhagic cystitis (HC), a severe yet rare condition often triggered by pelvic radiation therapy and specific chemotherapies, is characterized by gross hematuria and currently lacks approved drug treatment. Lipella's LP-10 stands at the forefront of addressing this unmet medical need.

About Oral Lichen Planus

Oral Lichen Planus (OLP) is a chronic, inflammatory, T-cell-mediated, autoimmune oral mucosal disease. It is a painful condition with malignant potential, and complications include infections, scarring, stress and depression. OLP affects approximately 6-7 million Americans. There is no approved pharmacotherapy and most currently available treatments are palliative.

About Graft-versus-Host Disease

Graft-Versus-Host Disease (GVHD) occurs when donor bone marrow or stem cells attack the recipient following a treatment for leukemia, lymphoma, and other hematological cancers. Oral manifestation of GVHD is frequently involved and is a rare and serious disease. Lipella has been granted orphan disease designation for LP-310 treatment of oral GVHD.

About Lipella Pharmaceuticals Inc.

Lipella Pharmaceuticals is a clinical-stage biotechnology company focused on developing new drugs by reformulating the active agents in existing generic drugs and optimizing these reformulations for new applications. Additionally, Lipella maintains a therapeutic focus on diseases with significant, unaddressed morbidity and mortality where no approved drug therapy currently exists. Lipella completed its initial public offering in December 2022. For more information, please visit www.lipella.com or 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.