Lipella Pharmaceuticals Announces U.S. Patent Allowance for Innovative Liposomal Drug Delivery Platform

October 15, 2024 05:00 ET

- ***Patent application covers key technology innovations for delivering therapeutic agents***
- ***Proprietary technology enables precise delivery to improve safety and efficacy in oncology, cancer survivorship and immunotherapy***
- ***Allowance provides broad IP protection for drug-delivery platform and extends market exclusivity for two lead clinical assets currently in Phase 2 trials***

PITTSBURGH, Oct. 15, 2024 (GLOBE NEWSWIRE) -- Lipella Pharmaceuticals Inc. (Nasdaq: LIPO), a clinical-stage biotechnology company focused on developing therapies for serious diseases with unmet medical needs, today announced the receipt of a notice of allowance from the U.S. Patent and Trademark Office (USPTO) for its proprietary liposomal drug delivery platform. The patent application, U.S. Patent No. 17/829,960, titled "Delivery of Agents Using Metastable Liposomes," covers key innovations in Lipella's platform technology for delivering therapeutic agents via liposome-based vehicles.

The patent allows claims that cover Lipella's method for using metastable liposomes to deliver a variety of therapeutic agents, including the company's lead assets, LP-10 and LP-310. This breakthrough technology enables precise, targeted delivery, improving the safety and efficacy of treatments across multiple therapeutic areas, including oncology, cancer survivorship, and immunotherapy.

Dr. Michael Chancellor, Chief Medical Officer of Lipella Pharmaceuticals, commented, "The allowance of this patent is a significant milestone for Lipella as it strengthens our intellectual property portfolio and supports our ongoing efforts to advance therapies for conditions such as hemorrhagic cystitis and oral lichen planus. Our liposomal drug delivery system offers a safer and more effective means of administering therapeutics like tacrolimus by targeting disease sites directly and minimizing the systemic side effects typically associated with these treatments."

This newly allowed patent provides broad intellectual property protection for Lipella's drug delivery platform, which optimizes delivery to epithelial tissues such as those lining the mouth, bladder, colon, esophagus, vagina, and urethra. It extends market exclusivity and strengthens Lipella's competitive position, particularly for its two lead clinical assets currently in Phase 2 trials. With additional patents covering the company's formulations in the U.S., Australia, and Canada until 2035, Lipella is poised for further growth and development as it continues to advance its clinical pipeline.

About Lipella's Lead Clinical Assets: LP-10 and LP-310

- LP-10 is a liposomal formulation of tacrolimus designed for intravesical administration to treat hemorrhagic cystitis (HC), a rare but severe condition characterized by bleeding from the bladder. LP-10 has shown promising safety and efficacy results in a multicenter Phase 2a trial, where it improved urinary symptoms

in patients. The FDA has granted Orphan Drug Designation to LP-10 for the treatment of moderate to severe HC, further underscoring its potential to address this critical unmet need. A Phase 2b multicenter placebo-controlled trial is ready to begin.

- LP-310 is an innovative oral rinse formulation of LP-10, designed to treat oral lichen planus (OLP), a chronic autoimmune disease affecting the mucous membranes of the mouth. LP-310 offers a promising new approach to treating OLP, which affects millions of Americans and currently lacks an approved pharmacotherapy. A Phase 2a multicenter trial is underway with anticipated top-line data by year-end and trial completion by mid-2025.

About Hemorrhagic Cystitis (HC)
Hemorrhagic cystitis is a serious condition often resulting from radiation therapy or chemotherapy, marked by severe bleeding in the bladder. With no FDA-approved drug treatments available, LP-10 is positioned to become a breakthrough therapy for patients suffering from this debilitating condition.

About Oral Lichen Planus (OLP)
Oral lichen planus is a chronic autoimmune disease that causes inflammation and lesions in the oral mucosa. It can lead to significant discomfort, scarring, and increased risk of oral cancer. Despite affecting six to seven million people in the U.S., there are no approved treatments, and current therapies offer only symptomatic relief.

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.

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.