Lipella Pharmaceuticals Announces Successful Top Line Results of Phase 2A Clinical Trial of LP-10

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Results to be Presented at BIOTECH SHOWCASE™ 2023 on Wednesday, January 11th at 2:00pm PST

PITTSBURGH, Jan. 11, 2023 /PRNewswire/ -- Lipella Pharmaceuticals Inc. (Nasdaq: "LIPO") ("Lipella," "our, "us" or the "Company"), 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, today announced top line results of the Company's recently completed Phase 2a clinical trial evaluating the safety and efficacy of its drug candidate LP-10 for Hemorrhagic Cystitis, a rare but highly morbid disease for which there are currently no FDA approved treatments.

Jonathan Kaufman, Chief Executive Officer, will present a corporate overview including the top-line results, at Biotech Showcase 2023™ on Wednesday, January 11th at 2:00pm PST at the Hilton San Francisco - Union Square, 333 O'Farrell Street, San Francisco, CA.

"The successful completion of the Phase 2a clinical trial of LP-10 is a critical milestone in Lipella's development," said Jonathan Kaufman, Ph.D., Chief Executive Officer of Lipella. "We're gratified with the results and look forward to our next step, which will be to communicate with the FDA on the study's results and the pathway forward to seeking regulatory approval for LP-10. The achievement of this milestone brings Lipella one step closer to providing a first-in class treatment for the cancer survivor community with hemorrhagic cystitis."

About the LP-10 Phase 2a Trial and Top Line Results

The LP-10 Phase 2a clinical trial was a multi-center, dose-escalation study (clinicaltrials.gov: NCT01393223). The study recruited 13 subjects with moderate to severe refractory hemorrhagic cystitis. These subjects were treated with up to two courses of LP-10 intravesical bladder instillations.

The top line results indicated:

- All subjects tolerated LP-10 instillations and completed the study without report of product related serious adverse events.
- LP-10 pharmacokinetic analysis demonstrated short duration of systemic uptake.
- A dose response was noted and there were
    - Decreased hematuria
    - Decreased cystoscopic bleeding and ulceration sites
    - Improved patients' urinary symptoms
- Responder analysis noted complete response in 3 subjects, partial response in 7 subjects and no response in 3 subjects.

About Hemorrhagic Cystitis

Lipella received Orphan Disease Designation LP-10 for the treatment of moderate to severe hemorrhagic cystitis, a disease with great unmet need and no currently approved drug treatment. Radiation used to treat prostate, colon, uterine, cervical and other pelvic cancers can cause chronic, painful urinary inflammation and blood loss called radiation hemorrhagic cystitis. Certain chemotherapies (such as cyclophosphamide) can also cause this painful form of urinary bleeding. The blood loss associated with hemorrhagic cystitis can lead to surgery and can be fatal.

About Lipella Pharmaceuticals Inc.

Lipella 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. We believe that this strategy combines many of the cost efficiencies and risk abatements derived from using existing generic drugs with potential patent protections for our proprietary formulations; this strategy allows us to expedite, protect, and monetize our product candidates. Additionally, we maintain a therapeutic focus on diseases with significant, unaddressed morbidity and mortality where no approved drug therapy currently exists, believing that this focus can potentially help reduce the cost, time and risk associated with obtaining marketing approval.

Forward-Looking Statements

This press release contains forward-looking statements. These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will," and variations of these words or similar expressions that are intended to identify forward-looking statements. Any such statements in this press release that are not statements of historical fact may be deemed to be forward-looking statements. These forward-looking statements include, without limitation, statements regarding the completion, timing and anticipated size of Lipella's initial public offering and the expected commencement of trading on the Nasdaq Capital Market.

Any forward-looking statements in this press release are based on our current expectations, estimates and projections only as of the date of this release and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, completion of Lipella's initial public offering on the anticipated terms, or at all, market conditions and the satisfaction of customary closing conditions related to such initial public offering. These and other risks concerning our product candidates and operations are described in additional detail in the Registration Statement on file with the SEC. We explicitly disclaim any obligation to update any forward-looking statements except to the extent required by law.