Landos Biopharma Publishes Results of NX-13 Phase 1b Study in Ulcerative Colitis in Journal of Crohn's and Colitis

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NX-13, a Novel, Oral, NLRX1 Agonist, was Observed to be Well Tolerated and Demonstrated Early Signs of Rapid Symptomatic Relief and Endoscopic Improvement in Patients with Ulcerative Colitis

NEXUS Phase 2 Proof-of-Concept Study is Ongoing, with Top-Line Readout Expected in Q4 2024

NEW YORK, Nov. 21, 2023 (GLOBE NEWSWIRE) -- Landos Biopharma, Inc. (NASDAQ: LABP), a clinical-stage biopharmaceutical company developing novel, oral medicines for patients with autoimmune diseases, today announced a peer-reviewed publication describing the safety, tolerability, pharmacokinetic and clinical efficacy results for the NX-13 Phase 1b trial in patients with ulcerative colitis (UC) in the *Journal of Crohn's and Colitis*.

"We are delighted to have our Phase 1b results of NX-13 in UC published in the Journal of Crohn's and Colitis," said Dr. Fabio Cataldi, Executive Vice-President & Chief Medical Officer at Landos. "The publication highlights the promising data that are the foundation for our ongoing NEXUS Phase 2 trial, which is on track for top-line readout in the fourth quarter of 2024."

The publication, titled "The Safety, Tolerability, Pharmacokinetics and Clinical Efficacy of the NLRX1 agonist NX-13 in Active Ulcerative Colitis: Results of a Phase 1b Study", reports the results of the Phase 1b trial which included 38 patients randomized to placebo (n=5), 250mg immediate release (IR) of NX-13 (n=11), 500mg IR of NX-13 (n=11) or 500mg delayed release NX-13 (n=11). NX-13 was found to be well tolerated in all patients studied. No deaths or severe adverse events were reported and all adverse events were mild to moderate.

The majority of patients treated with NX-13 for four weeks showed consistent and rapid clinical improvement in total Mayo score and in symptoms relief (as measured by rectal bleeding and stool frequency). Additionally, the endoscopic improvement observed correlated closely with symptoms improvement.

"Despite advances in UC treatments, the need for new and novel therapies such as NX-13 remains highly important for patients," commented Bram Verstockt, M.D., Ph.D., and lead author. "The early signs of efficacy, along with a favorable safety profile, highlighted in this publication are encouraging. I am excited about the potential of NX-13 and immunometabolism in breaking the inflammatory cycle in UC, which remains a significant unmet need in effectively treating patients."

NX-13 is currently being evaluated in the NEXUS trial, a randomized, multicenter, double-blind, placebo-controlled, multiple dose, statistically powered, Phase 2 proof-of-concept study (NCT05785715) with top-line results expected in the fourth quarter of 2024.

About Landos Biopharma

Landos Biopharma is a clinical stage biopharmaceutical company focused on the development of first-in-class, oral therapeutics for patients with autoimmune disease. Our mission is to create safer and more effective treatments that address the therapeutic gap in the current treatment paradigm.

We have a portfolio of novel targets anchoring two libraries of immunometabolic modulation pathways, including four potentially first-in-class, once-daily, oral therapies targeting eight indications in the immunology space.

We are currently focused on advancing the clinical development of NX-13 in UC. We initiated the NEXUS Phase 2 proof-of-concept trial in April 2023 and expect to report top-line results in the fourth quarter of 2024.

For more information, please visit www.landosbiopharma.com.

Cautionary Note on Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects for Landos Biopharma, Inc. (the "Company"), including statements about the Company's strategy, clinical development and regulatory plans for its product candidates and other statements containing the words "anticipate", "plan", "expect", "may", "will", "could", "believe", "look forward", "potential", the negatives thereof, variations thereon and similar expressions, or any discussions of strategy constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation and enrollment of current and future clinical trials, including the ongoing Phase 2 trial of NX-13, availability and timing of data from ongoing clinical trials, expectations for regulatory approvals, other matters that could affect the availability or commercial potential of the Company's product candidates, our anticipated cash runway and other similar risks. Risks regarding the Company's business are described in detail in its Securities and Exchange Commission ("SEC") filings, including in its Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q, which are available on the SEC's website at www.sec.gov. Additional information will be made available in other filings that the Company makes from time to time with the SEC. In addition, the forward-looking statements included in this press release represent the Company's views only as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so, except as may be required by law. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

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