Landos Biopharma Announces First Patient Dosed in a Phase 1b Study of NX-13 for Ulcerative Colitis

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Landos' second first-in-class product candidate designed to provide a safer and more convenient treatment for ulcerative colitis patients

Topline results are expected in the first quarter of 2022

BLACKSBURG, Va., April 29, 2021 (GLOBE NEWSWIRE) -- Landos Biopharma (NASDAQ: LABP), a clinical-stage biopharmaceutical company focused on the discovery and development of therapeutics for patients with autoimmune diseases, today announced that the Company dosed the first patient in a Phase 1b study of NX-13 for ulcerative colitis (UC). NX-13 is Landos' potentially first-in-class, novel, orally administered, gut-restricted NLRX1 agonist for the treatment of UC and Crohn's disease (CD).

"UC is a chronic and debilitating disease that impairs the quality of life of millions of patients worldwide, with many relapsing in less than a year after receiving currently available therapies. Our novel oral product candidate, NX-13, is designed to initiate a robust multimodal mechanism and restore immune tolerance in patients with UC, both as a single agent or in combination with other therapeutics," commented Josep Bassaganya-Riera, Ph.D., Chairman, President, and CEO of Landos Biopharma. "Our rapid advancement of NX-13 to a Phase 1b trial in just over a year is supportive of our differentiated approach to target the NLRX1 pathway, which can favorably modulate epithelial barrier integrity and interactions with the gut microbiome, while decreasing reactive oxygen species formation and inflammation in the GI tract. As our second first-in-class product candidate to enter the clinic, NX-13 is quickly progressing through clinical development in UC and will soon enter clinical testing for CD as well as for other autoimmune diseases."

The Phase 1b study is a randomized, placebo-controlled, double-blind, multicenter, dose ranging study, evaluating 40 subjects with active UC over 28 days. All subjects will be randomized to receive one of the three NX-13 treatment regimens: 250 mg immediate release tablets (IR), 500 mg IR, 500 mg modified release tablets (MR) or placebo. The objective of the trial will be to evaluate the safety and pharmacokinetics of multiple dose levels of NX-13 in patients. Exploratory biomarkers of response to treatment, including fecal calprotectin, will also be evaluated. In March, Landos announced successful completion of a Phase 1a study of NX-13 in normal healthy volunteers, which identified a maximum tolerated dose 10-fold greater than the anticipated therapeutic dose, validated the gut-restricted profile of NX-13, and demonstrated a preliminary signal of response in reduction of fecal calprotectin levels.

"After clearing 5 investigational new drug applications with the FDA and with three clinical trials completed, a Phase 2 trial for omilancor about to be initiated in CD, in addition to the Phase 1b trial of NX-13 in UC patients, we continue to accelerate the clinical development of our top product candidates in our expansive therapeutic pipeline. We expect to quickly report topline data for this Phase 1b trial of NX-13 in the first quarter of 2022," said Jyoti Chauhan, EVP of Operations & Regulatory Affairs of Landos Biopharma.

About Ulcerative Colitis (UC)
UC is a chronic, autoimmune, inflammatory bowel disease that causes inflammation, irritation, and ulcers in the lining of the large intestine (colon) and rectum. Symptoms include abdominal pain, rectal pain and bleeding, bloody stools, diarrhea, fever, weight loss, and malnutrition. Having UC puts a patient at increased risk of developing colon cancer. Diagnosis typically occurs in early adulthood and the disease requires maintenance treatment for the remainder of the patient's life. UC is estimated to affect over 900,000 patients in the United States and over 1 million patients throughout the rest of the world. With 70% of addressable patients experiencing a second flare within one year and 30% of patients in remission failing to stay in remission for more than one year, there is an unmet medical need in UC for safer and more efficacious therapeutics.

About NX-13
NX-13 is a first-in-class, orally-active, gut-restricted, small molecule therapeutic candidate for the treatment of ulcerative colitis (UC) and Crohn's disease (CD). NX-13 targets NLRX1, a mitochondria-associated receptor with the ability to modulate immune responses. By activating the NLRX1 pathway, NX-13 increases autophagy and oxidative phosphorylation in immune cells while decreasing differentiation of effector CD4+ T cells, reactive oxygen species, inflammasome formation and production of inflammatory cytokines. The Company reported positive results from the Phase 1a study of NX-13 in healthy volunteers in Q1 2021 and initiated a Phase 1b study of NX-13 in patients with ulcerative colitis in Q2 2021.

About Landos Biopharma
Landos Biopharma is a clinical-stage biopharmaceutical company focused on the discovery and development of oral therapeutics for patients with autoimmune diseases that are the first to target new mechanisms of action, including the LANCL2, NLRX1 and PLXDC2 immunometabolic pathways. Landos Biopharma's core expertise is in the development of therapeutic candidates targeting novel pathways at the interface of immunity and metabolism. Lead asset omilancor is a novel, oral, gut-restricted small molecule therapeutic candidate for the treatment of ulcerative colitis, Crohn's disease and Eosinophilic Esophagitis that targets the LANCL2 pathway. NX-13 is a novel, oral, gut-restricted compound for the treatment of inflammatory bowel disease, which targets the NLRX1 pathway. Additional candidates are in development for the treatment of lupus nephritis, rheumatoid arthritis, multiple sclerosis, and diabetes. For more information, please visit www.landosbiopharma.com.

Cautionary Note on Forward-Looking Statements
Any 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 of the company's therapeutic candidates, the Company's anticipated milestones and future expectations and plans and prospects for the Company and other statements containing the words "subject to", "believe", "anticipate", "plan", "expect", "intend", "estimate", "project", "may", "will", "should", "would", "could", "can", the negatives thereof, variations thereon and similar expressions, or by 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 future clinical trials,

expectations of expanding ongoing clinical trials, 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 and other similar risks. 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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