Landos Biopharma Announces Positive Results from a Phase 1 Study of NX-13 in Healthy Volunteers

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NX-13 was well tolerated with no reported serious adverse events

All primary and secondary endpoints in the Phase 1 study of NX-13 were met

Landos expects to initiate a Phase 1b trial of NX-13 in patients with ulcerative colitis (UC) later this year

BLACKSBURG, Va., March 04, 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 NX-13, the Company's first-in-class novel, orally administered therapeutic candidate for the treatment of inflammatory bowel disease (IBD), has successfully met all primary and secondary endpoints in a Phase 1 study. The data showed that NX-13 was well tolerated following evaluation of multiple doses over one and seven days compared with placebo.

"The favorable results from this trial underscore the promise of NX-13's novel multimodal mechanism of action, targeting the NLRX1 pathway locally in the GI tract, and its potential to bring a new approach to treating patients with IBD," commented Josep Bassaganya-Riera, Chairman, President and Chief Executive Officer of Landos. "As a part of our growing franchise of gut-restricted, oral therapeutics for ulcerative colitis (UC) and Crohn's disease (CD) with novel immunometabolic mechanisms, we are excited that NX-13 met all primary and secondary endpoints in this first-in-humans study."

"By using Landos' powerful LANCE discovery and development platform, we have identified three novel mechanisms of therapeutic efficacy (LANCL2, NLRX1 and PLXDC2) and developed seven novel product candidates around those targets. Our lead product candidates (BT-11 and NX-13) are in clinical testing and our development pipeline currently targets up to 14 autoimmune disease indications. We are pleased that it took only 18 months for NX-13 to advance from discovery to Phase 1 clinical testing and we are looking forward to initiating a Phase 1b trial in patients with UC later this year," commented Raquel Hontecillas, PhD, Chief Scientific Officer of Landos.

The Phase 1 trial was a randomized, double-blind, placebo-controlled single and multiple ascending dose study designed to evaluate the safety, tolerability and pharmacokinetics of NX-13, which was orally administered. The single ascending dose arm consisted of 35 healthy volunteers in a total of five cohorts (250 to 4,000 mg). The multiple ascending dose arm consisted of 21 healthy volunteers enrolled in a total of three cohorts (1,000 to 4,000 mg). Within each cohort in both dose arms, five participants received NX-13 and two participants received placebo. Across the eight cohorts, no SAEs were reported. The maximum tolerated dose was identified to be 10-fold greater than the anticipated therapeutic dose.

Following the positive results from the Phase 1 study, Landos plans to initiate a Phase 1b trial of NX-13 in patients with ulcerative colitis in 2021. Additionally, building on the success of the LANCE computational platform in BT-11 and NX-13, Landos anticipates filing at least three new INDs in 2021.

About NX-13

NX-13 is a first-in-class, orally active, gut-restricted, small molecule therapeutic candidate for the treatment of inflammatory bowel disease. NX-13 targets NLRX1, a mitochondria-associated receptor with the ability to modulate immune responses. By activating the NLRX1 pathway, NX-13 is designed to increase oxidative phosphorylation in immune cells, reduces differentiation of effector CD4-positive T cells, and decrease production of inflammatory cytokines.

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 BT-11 is a novel, oral, gut-restricted small molecule therapeutic candidate for the treatment of ulcerative colitis and Crohn's disease 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.

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