Landos Biopharma Announces Positive Results from a Phase 2 Trial of Oral BT-11 for Patients with Ulcerative Colitis

January 4, 2021

-Once a day oral dosing with BT-11 induced placebo-adjusted clinical remission rates of up to 11.5% at week 12-

-A small subset of biologic-experienced patients also showed positive trends in clinical remission rates-

-Normalization of biomarkers such as fecal calprotectin observed after 2 weeks of oral dosing-

-BT-11 was well tolerated with a similar adverse event profile across placebo and BT-11 groups-

-Landos plans to initiate a Phase 3 trial of BT-11 in ulcerative colitis patients and a Phase 2 trial of BT-11 in Crohn's disease patients in 2021-

BLACKSBURG, VA., January 4th, 2021 – Landos Biopharma, a clinical-stage biopharmaceutical company focused on the discovery and development of therapeutics for patients with autoimmune diseases, today announced positive results from a first-in-patients 12-week Phase 2 proof-of-concept trial of BT-11, a novel, orally administered, gut-restricted LANCL2 modulator in patients with mild to moderate ulcerative colitis (UC).

"We are excited by the very promising Phase 2 trial results evaluating BT-11, as it marks the first potential therapeutic to engage the novel target LANCL2. We believe this novel mechanism of action is responsible for modulating key immunological mechanisms associated with various autoimmune diseases such as ulcerative colitis and Crohn's disease," said Josep Bassaganya-Riera, Chairman, President and Chief Executive Officer of Landos. "These proof-of-concept results de-risk BT-11 and provide validation of the LANCL2 pathway and its potential as a new therapeutic approach for treating UC and a wide range of autoimmune diseases. This positive outcome also validates our advanced modeling and AI-based LANCE precision medicine platform, which efficiently identifies immunometabolic targets and develops novel product candidates designed to engage these conserved pathways, providing durable therapeutic activity. Building on the momentum from this Phase 2 trial, Landos will continue expanding its robust therapeutic inflammation and immunology pipeline, which currently contains seven product candidates based on novel immunometabolic mechanisms targeting a wide range of autoimmune diseases."

"The clinical remission rates observed in these initial BT-11 Phase 2 results compare favorably to standard of care treatments. However, as an oral, gut-restricted once a day tablet that targets LANCL2, Landos' product candidate is designed to be well tolerated, avoid the serious side effects of systemic treatments and offer more convenience for patients. BT-11's encouraging results indicate its potential to transform the treatment paradigm for patients with ulcerative colitis. I look forward to seeing additional exciting clinical results in more patients in Phase 3 registrational clinical trials," commented Jean-Frederic Colombel, MD, a Gastroenterologist at Mount Sinai School of Medicine.

The objective of the Phase 2 trial was to evaluate the safety and efficacy of BT-11 compared to placebo in subjects with mild to moderate UC. The Phase 2 study is a randomized, placebo-controlled, double-blind, parallel-group multicenter study which enrolled 198 UC patients in 53 sites throughout the U.S., Europe and Russia. Dosing was explored in two BT-11 cohorts (500 mg QD and 1,000 mg QD) or placebo (randomized 1:1:1) and clinical remission was analyzed over a 12-week induction period, as defined by the 3-component modified Mayo Score, using a rectal bleeding subscore of 0, a stool frequency subscore of 0 or 1, and an endoscopic subscore of 0 or 1. In the intent-to-treat (ITT) population, a positive trend in absolute clinical remission rates for the 1,000 and 500 mg doses compared to placebo was observed (31.8% and 30.3% versus 22.7%; p=0.340 and 0.235). The resulting placebo-adjusted clinical remission rates of 9.1% and 7.6% for the 1,000 and 500 mg dose groups, respectively, are consistent with standard of care treatments in both mild to moderate and moderate to severe UC. In a more moderate subset of patients (with Mayo score equal to or greater than 7 at baseline) the placebo-adjusted clinical remission rate was (11.5%; p=0.153 and 8.7% p=0.273) for the 1,000 (n=47) and 500 mg (n=44) dose groups respectively versus placebo (n=50). Additionally, in a small subset of biologic experienced patients, positive placebo-adjusted remission trends were also observed (66% and 33% in the 1,000 (n=3) and 500 mg (n=3) cohorts versus placebo n=3, 0%).

Normalization of fecal calprotectin levels, commonly cited to be one of the most predictive biomarkers of response to treatment in UC and Crohn's disease, was detectable in a subset of patients (n=106) with abnormal baseline calprotectin levels (>250 ug/g), after 2 weeks of oral dosing in over 40% of patients treated with BT-11 (n=64), at either dose level, when compared to 21% of patients receiving placebo (n=42). Additionally, the ability of BT-11 to normalize fecal calprotectin levels was maintained for the entire 12-week period. Notably, in patients with elevated baseline fecal calprotectin levels (>250 ug/g), an indication of active disease, BT-11 dosing provided a placebo-adjusted clinical remission rate of up to 13.1%.

BT-11 was well tolerated with similar adverse events across placebo and BT-11 groups. Pharmacokinetic measurements confirmed dose proportional increases of BT-11 in stool samples across each dosing group. BT-11 was confirmed to be gut-restricted with no evidence of greater systemic absorption or increased exposure over time in UC patients relative to normal healthy volunteers. BT-11 stool concentrations were stable between 2 and 12 weeks of dosing.

With the Phase 2 study results in hand demonstrating proof-of-concept clinical efficacy and safety of BT-11 for patients with mild to moderate UC, Landos plans to advance development of this product candidate with a Phase 3 trial in 2021. The Phase 3 trial of BT-11 will evaluate induction of clinical remission at week 12 and maintenance of clinical remission at week 52 in patients with UC. Additionally, the Company plans to initiate its Phase 2 trial of BT-11 for 150 patients with moderate to severe Crohn's disease in the first half of 2021.

About BT-11

BT-11 is a novel, orally-active, gut-restricted small molecule investigational drug that targets the Lanthionine Synthetase C-Like 2 (LANCL2) pathway impacting the gastrointestinal tract. LANCL2 plays an important role in the immunoregulatory process. By activating the LANCL2 pathway and modulating the interactions between immunological and metabolic signals in immune cells, BT-11 is designed to create a favorable regulatory microenvironment in the gut, decreasing the production of key inflammatory mediators and increasing anti-inflammatory markers in regulatory T cells (Treg) within the site of inflammation. BT-11 has shown demonstrated therapeutic activity in 5 preclinical models of IBD, a benign safety profile without the concerns of systemic exposure in preclinical and Phase 1 clinical studies and has two open INDs for evaluation in UC and CD. The Company completed Phase 1 testing of BT-11 in 2018 and initiated Phase 2 testing in 2019.

About Landos Biopharma

Landos Biopharma, Inc. is a clinical-stage biopharmaceutical company focused on the discovery and development of novel oral therapeutics for patients with autoimmune diseases. Lead asset BT-11 is a novel, oral, gut-restricted 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 and the second agent in the pipeline for the treatment of inflammatory bowel disease, which targets the NLRX1 pathway and successfully completed Phase 1 clinical testing. Landos' therapeutic inflammation and immunology pipeline currently contains seven product candidates targeting 14 disease indications. Additional candidates are in development for the treatment of lupus nephritis, rheumatoid arthritis, multiple sclerosis, Alzheimer's disease, plaque psoriasis, atopic dermatitis, eosinophilic esophagitis, asthma, allergy, COPD, NASH, diabetic nephropathy, and type 1 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.

Contacts:
Thomas Hoffmann (investors)
Solebury Trout
646-378-2931
thoffmann@troutgroup.com

Hannah Gendel (media)

Solebury Trout

646-378-2943

hgendel@troutgroup.com