Landos Biopharma Announces Publication of Results from First-in-Human Phase 1 Study of BT-11 in Healthy Volunteers

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Landos Biopharma, Inc., a clinical-stage biopharmaceutical company focused on the discovery and development of first-in-class, oral therapeutics for patients with autoimmune diseases, announced the publication of Phase 1 results of BT-11, its orally-active, gut-restricted investigational new drug (IND) for Crohn's disease (CD) and ulcerative colitis (UC), in the IBD Journal published in association with the Crohn's & Colitis Foundation**.** The first-in-human, Phase 1 single ascending dose (SAD) and 7-day multiple ascending dose (MAD) studies showed that BT-11 treatment is well-tolerated with no dose-limiting toxicities, and no detectable systemic immunosuppression up to daily oral doses of 100 mg/kg.

"The results of our Phase 1, first-in-human clinical study showed that the adverse event (AE) profile between placebo and BT-11 cohorts were comparable, and verified gut-restricted activity with minimal BT-11 systemic absorption, " said Dr. Josep Bassaganya-Riera, Chairman and CEO of Landos. "These Phase 1 clinical results reinforce BT-11's safety profile and show lower concentrations of fecal calprotectin, a predictive biomarker of therapeutic response and extended clinical remission in both UC and CD. These results support our plans to advance the evaluation of BT-11 to Phase 2 therapeutic efficacy studies in UC and CD patients."

The publication***, Safety, tolerability, and pharmacokinetics profile of BT-11, an oral, gut-restricted LANCL2 agonist investigational new drug for IBD: A randomized, double-blind, placebo-controlled Phase I clinical trial***, was authored by researchers at Landos; the Icahn School of Medicine at Mount Sinai, NYC, NY; and Royal Adelaide Hospital, Adelaide, Australia. In the study, oral BT-11 was assessed for safety, tolerability and Pharmacokinetics in 70 normal healthy volunteers in a randomized, double-blind, placebo-controlled trial. Subjects were randomized into five single ascending dose cohorts (up to 100 mg/kg, p.o.) and three multiple ascending dose cohorts (up to 100 mg/kg QD for seven days, p.o.). Safety and tolerability were assessed by adverse event reporting, vital signs, ECG, hematology and clinical chemistry. BT-11 did not increase total or gastrointestinal AE rates relative to placebo, with no serious adverse events (SAE) observed. Oral BT-11 dosing did not result in any clinically significant findings by biochemistry, coagulation, ECG, hematology, or urinalysis when compared to placebo.

Additional details from the study:

- The study found that fecal concentrations of BT-11 were 6,000-fold higher than maximum plasma concentrations. We believe this gut-restriction in humans validates the local actions of BT-11 observed preclinically in animal models, in which plasma concentrations of BT-11 were less than 0.1% of fecal concentrations.
- BT-11 did not induce any effect on vital signs, cardiovascular or respiratory function, no systemic immune effects were observed. Clinical laboratory results additionally support a lack of hepatic and renal toxicities in the study.
- BT-11 did not result in a decrease in White Blood Cell count or other hematology related parameters, which suggests that given its gut-restricted activity, BT-11 may reduce or avoid systemic immunosuppression. These initial results are consistent with findings from nonclinical studies and suggest a lower risk for systemic immunosuppression with BT-11 as opposed to systemic IBD drugs.
- Doses of 7-14 mg/kg in the form of a once daily tablet are expected to be evaluated in Phase II studies in IBD patients for therapeutic effect. The results of this Phase 1 study suggest a wide safety margin (7- to 15-fold compared to clinical doses to be studied) in human subjects.
- Fecal calprotectin is believed to be a predictive biomarker in IBD, is a key diagnostic test for differentiating UC and CD from IBS. Over 99% of IBD patients have elevated calprotectin and is predictive of relapse. In this study, fecal calprotectin levels were lower in all BT-11 treated groups when compared to placebo.

Landos will present these results at the 2019 Digestive Disease Week® (DDW) in San Diego, CA. The poster "TU1754: SAFETY AND TOLERABILITY OF BT-11, A GUT-RESTRICTED LANCL2 AGONIST, IN A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE I STUDY IN NORMAL HEALTHY VOLUNTEERS" will be presented by Andrew Leber, PhD, Scientific Director of Landos, in the IBD: Controlled Clinical Trials in Humans session, Clinical Practice, Inflammatory Bowel Diseases track, Tuesday, May 21, 2019 from 12:00 PM – 2:00 PM.

About BT-11

Landos' lead clinical asset, BT-11, is a novel, oral, gut-restricted investigational new drug (IND) targeting the Lanthionine Synthetase C-Like 2 (LANCL2) pathway in the gastrointestinal tract for the treatment of Crohn's disease (CD) and ulcerative colitis (UC). BT-11 is designed to intercept IBD by decreasing the production of inflammatory mediators and increasing anti-inflammatory markers within the gastrointestinal tract. BT-11 has shown positive therapeutic activity in preclinical models of inflammatory bowel disease (IBD), a favorable safety profile, and has two open INDs for evaluation in UC and CD. The Company completed Phase 1 testing of BT-11 in 2018 and plans to initiate Phase 2 testing in 2019.

About IBD

IBD represents a group of chronic and disabling disorders that greatly impacts a patient's quality of life. The two primary clinical manifestations of IBD – Crohn's disease (CD) and ulcerative colitis (UC) – afflict 3 million Americans and 5 million people worldwide, with nearly 25% growth in prevalence over the last five years. There is an unmet clinical need for safer, more effective medications for these diseases as currently marketed therapeutics

have a number of drawbacks: they only benefit a small number of the overall population, lose response effectiveness, or cause high rates of serious side effects, including cancer, infection, and death.

About Landos Biopharma

Landos Biopharma, Inc. is a clinical-stage biopharmaceutical company focused on the discovery and development of first-in-class oral therapeutics for patients with autoimmune diseases. Landos' lead clinical asset, BT-11, is a first-in-class, oral therapeutic that acts locally in the gastrointestinal tract for treatment of inflammatory bowel disease (IBD). The company has completed Phase 1 clinical testing and will initiate a Phase 2 clinical program for BT-11 for treatment of UC and CD in 2019. Landos also has a robust pipeline of new compounds for other autoimmune diseases, several of which will advance to IND in 2019. Landos is headquartered in Blacksburg, VA. For more information, please visit www.landosbiopharma.com or contact info@landos.comocreative.com or follow us @Landosbio.

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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