Landos Biopharma Announces First Patient Dosed in a Phase 2 Study of Omilancor for Moderate-to-Severe Crohn's Disease

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Company's second omilancor program entering a Phase 2 study with plans to pursue at least five autoimmune indications

Topline results are expected in the second quarter of 2022

BLACKSBURG, Va., May 06, 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 has dosed the first patient in a Phase 2 study of omilancor, Landos' novel, orally administered, gut-restricted LANCL2 agonist, for the treatment of moderate-to-severe Crohn's disease (CD).

"We are extremely proud of the momentum we have generated this year with the clinical advancement of omilancor, as this trial marks the second indication after ulcerative colitis which is Phase 3-ready," commented Josep Bassaganya-Riera, Chairman, President and Chief Executive Officer of Landos. "Initiating this Phase 2 trial is instrumental in supporting our efforts to showcase omilancor's ability to exert strong anti-inflammatory effects within the gastrointestinal tract through a novel mechanism of action. With no safe, convenient treatment maintenance options available for the over 100,000 patients worldwide living with moderate-to-severe CD, we believe omilancor, as an oral therapeutic designed to have higher tolerability and a gut-restricted PK profile, may provide a significantly improved therapeutic option."

This Phase 2 trial is a randomized, double-blind, placebo-controlled, parallel group, multicenter study designed to evaluate the proof of concept efficacy and safety of omilancor for the treatment of moderate-to-severe CD. Approximately 150 subjects will be randomized to receive either 1000 mg of omilancor or placebo. Treatment will be evaluated over a 12-week induction period followed by an 18-week maintenance period and 2-week post-treatment safety follow up. The co-primary endpoints will assess clinical remission at Week 12, defined by CDAI < 150, as well as the frequency and severity of AEs compared to placebo. The key secondary endpoints will evaluate the effects of omilancor on disease activity as measured by symptoms, colonoscopy, histology, and biomarkers as well as the health-related quality of life and pharmacokinetic parameters of this product candidate.

"There remains an unmet need for safer, more convenient and effective therapeutic alternatives to treat patients with CD," said Jean-Frederic Colombel, MD, Director, IBD Center at the Icahn School of Medicine at Mount Sinai and Landos Clinical Advisory Board member. "Oral treatment with omilancor has consistently demonstrated a benign and well-tolerated safety profile, a gut-restricted distribution without systemic immunosuppression, biologic-like efficacy signal and enhanced immunoregulatory mechanisms in UC patients. Based on these encouraging results, we believe omilancor could show similar levels of efficacy in CD patients with a well-tolerated safety profile and ultimately provide long-term benefit for millions of people living with IBD."

About Crohn's Disease (CD)

CD is a chronic, autoimmune, inflammatory bowel disease that causes inflammation, irritation and ulcers in any segment of the gastrointestinal tract. CD impacts the end of the small bowel and beginning of the colon most commonly, which in turn can lead to symptoms of abdominal pain, increased abdominal sounds, rectal pain and bleeding, bloody stools, diarrhea, fever, weight loss and malnutrition. There are four classes of CD and treatment depends on the level of severity. Current therapeutic options for severe disease, primarily biologics, have several limitations, which include but are not limited to safety risks for malignancies and infections, limited efficacy and lack of long-term maintenance options. There is an urgent need to establish a consensus for a first-line therapy for CD and improve upon the existing constraints in administration and efficacy.

About Omilancor (BT-11)

Omilancor 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, omilancor 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. The Company reported initial Phase 2 results of omilancor evaluating patients with ulcerative colitis in 2021 and expects to initiate a Phase 3 trial in the second half of 2021. Additionally, Landos initiated a Phase 2 trial of omilancor in patients with Crohn's disease in the first half of 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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