# Landos Biopharma Announces FDA Clearance of IND Application for Omilancor for the Treatment of Eosinophilic Esophagitis

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**Third potential indication for omilancor (BT-11), a first-in-class candidate for the treatment of autoimmune diseases**

BLACKSBURG, Va., April 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 U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for omilancor (BT-11), a novel, orally administered, gut-restricted LANCL2 agonist, in development for the treatment of Eosinophilic Esophagitis (EoE). With up to 160,000 patients in the United States, EoE is an orphan disease without a current FDA-approved therapeutic. Landos expects to initiate patient dosing in the first half of 2022.

"The clearance of this IND for our lead asset omilancor for a third indication, Eosinophilic Esophagitis, exemplifies the candidate's versatility to potentially target and treat multiple autoimmune diseases that face significant treatment challenges," commented Josep Bassaganya-Riera, Chairman, President and Chief Executive Officer of Landos. "EoE results from a dysregulation of Th2-mediatied immunity that can cause inflammation, chronic pain and frequent hospitalizations, of which approximately one third of patients do not respond to the current standard of care. Based on the trials we have conducted to date, we believe omilancor's established safety and tolerability profile and efficacy in reducing inflammation through the activation of LANCL2 supports the promise of omilancor to treat this underserved patient population."

This trial is a randomized, double-blind, placebo-controlled Phase 1b study designed to evaluate the safety and pharmacokinetics of omilancor in patients with active Eosinophilic Esophagitis (EoE). A total of 36 patients will be randomized in a 1:1:1 ratio to receive either omilancor 500 mg twice daily, omilancor 1000 mg once daily, or placebo for 12 weeks. Each of the treatment arms will include 12 subjects. The safety primary endpoint will measure the frequency and severity of adverse events as well as changes in clinical chemistry and hematology from baseline. The secondary endpoint is pharmacokinetic analysis of omilancor plasma levels at various time intervals post-dosing in addition to evaluating the mean concentration of omilancor in esophageal biopsy tissue after 12 weeks of dosing.

**About Eosinophilic Esophagitis**

Eosinophilic Esophagitis is a chronic disease of the esophagus that stems from an excessive Th2 response in the esophagus that is thought to result from increased stimulation by epithelial cells and dendritic cells. The inflamed esophagus can cause chronic pain, frequent hospitalizations and emergency room visits, difficulty eating or swallowing and formation of fibrotic structures. With no FDA-approved treatments for this disease, current management of EoE often consists of proton pump inhibitors, corticosteroids or inhaled medications typically used for asthma. Therapeutic candidates in development are primarily corticosteroids and biologics; however, these are likely to have similar limitations to those observed in IBD, including a presence of side effects and loss of response over time. Given the prevalence of EoE within both pediatric and adult populations, there is an unmet need for therapeutics with limited risk for side effects.

**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 plans to initiate 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.

**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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