Landos Biopharma Provides Comprehensive Update on Clinical Development Plans

January 5, 2023

Advancing NX-13 Clinical Development for Treatment of Ulcerative Colitis

On Track to Initiate Phase 2 Proof-of-Concept Trial for NX-13 in the Second Quarter of 2023 and Report Topline Data by the Fourth Quarter of 2024

Broader, Novel Pipeline Poised for Partnering and Continued Development in the Future;
Significant Optionality for Omilancor, LABP-104 and Four Promising Pre-Clinical Programs

Secures Additional $16.7 Million Investment

Disciplined Financial Approach Expected to Maintain Cash Runway into First Half of 2025

Company to Host Investor Call at 8:00 AM ET

NEW YORK, Jan. 05, 2023 (GLOBE NEWSWIRE) -- Landos Biopharma, Inc. (NASDAQ: LABP) ("Landos" or the "Company"), a clinical-stage biopharmaceutical company developing novel, oral medicines for patients with autoimmune diseases, today announced a comprehensive update on its future clinical development plans.

The Landos leadership team and Board of Directors have conducted an in-depth review of the Company's pipeline and overall development plans to ensure that it is pursuing the most promising therapies and target indications. Following the review of Landos' three clinical stage programs – NX-13, Omilancor and LABP-104 – as well as its four pre-clinical assets, Landos will be focused on advancing NX-13, a novel, oral, gut-selective NLRX1 agonist in development as a once-daily treatment for Ulcerative Colitis ("UC"), including into an upcoming Phase 2 proof-of-concept clinical trial.

"After thorough analysis and careful consideration, we are confident that focusing our resources toward NX-13's clinical development has the potential to deliver the most value for Landos and our shareholders," said Gregory Oakes, President and Chief Executive Officer of Landos. "Given the strong clinical data we saw in prior NX-13 trials and our anticipated timeline for the Phase 2 trial, we believe that advancing its development is the right path forward. NX-13, with its unique mechanism of action ("MOA"), favorable safety profile, once-daily dosing, and promising early clinical data, could potentially transform the current treatment paradigm with earlier utilization in moderate-to-severe UC for patients who are either failing or starting to lose efficacy on conventional therapies like 5-ASAs or steroids. Following the positive read-out of the NX-13 Phase 1b trial, we have been finalizing the design for a Phase 2 proof-of-concept clinical trial. Our goal is to generate as much meaningful data as possible, as quickly as possible, to build on our already impressive data foundation. We expect that the NX-13 Phase 2 trial will have two active arms and will be blinded, placebo-controlled, and statistically powered. We have already completed a series of startup activities and are on track for first site activation and patient enrollment in the second quarter of 2023. We look forward to sharing our progress and expect to report topline data by the fourth quarter of 2024."

Given the strong foundation of data across its broader pipeline, Landos believes Omilancor, LABP-104 and its novel preclinical programs are poised for partnering and continued clinical development in the future. Landos will continue to explore collaborations and other arrangements that would provide additional resources and/or capabilities to advance these promising programs and create value for shareholders.

"Our goal is to evolve Landos from a discovery-based organization into an immunology development powerhouse. We are focused on the successful advancement of our innovative pipeline of multiple pathways and programs with novel MOAs. We continue to see significant optionality for our broader pipeline, including Omilancor for UC, Crohn's Disease ("CD"), Eosinophilic Esophagitis, Psoriasis, and Atopic Dermatitis; LABP-104 for Systemic Lupus Erythematosus ("SLE") and Rheumatoid Arthritis ("RA"); as well our preclinical programs: LABP-66 for the treatment of Multiple Sclerosis ("MS"), Alzheimer's Disease, and other debilitating central nervous system ("CNS") diseases; LABP-73 for Respiratory Inflammatory disease; LABP-69 for RA and Diabetic Nephropathy; and LABP-111 for Nonalcoholic Steatohepatitis ("NASH") and Diabetes. We believe that potential partners, key opinion leaders, academics, and others are excited about these programs, and we will continue to engage with them to explore opportunities that would create long-term value for our shareholders. As we look ahead, we believe these programs have significant optionality for continued development in the future," continued Mr. Oakes.

Adding Key Talent and Capabilities

Landos has also been selectively enhancing its leadership team, adding key talent and capabilities to help position the Company for continued success as it advances NX-13 towards a Phase 2 proof-of- concept trial. Landos has added experts with significant clinical drug development expertise in the immunology space, including the appointment of Fabio Cataldi, MD, as Executive Vice President & Chief Medical Officer in September 2022. Dr. Cataldi brings more than twenty years of experience to Landos in the successful development of innovative therapies, including research expertise in gastroenterology and immunology, particularly in UC.

Partnership with LianBio

As announced in 2021, Landos entered into an exclusive collaboration and license agreement with LianBio for the development and commercialization of NX-13 and Omilancor in Greater China, including mainland China, Hong Kong, Taiwan, and Macau, as well as other select Asian markets. Of note, the Company continues to maintain rights to Japan, which Landos believes is a significant and growing market opportunity.

Clinical Stage Programs

NX-13
NX-13 is a novel, oral, gut-selective NLRX1 agonist in development for the once-daily treatment of UC.

- Landos announced top-line results from its NX-13 Phase 1b trial in UC patients in August 2022. The data showed favorable safety and tolerability profiles across a range of doses, as well as signals of clinical improvement as soon as two weeks in patients' symptoms and four weeks by endoscopy in exploratory endpoints. This early signal, as well as the data from long-term toxicology studies, support the potential of NX-13 as an important new treatment for UC.

- Landos is continuing an in-depth analysis of the clinical, pharmacokinetic ("PK"), and pharmacodynamic ("PD") data for NX-13. A preliminary analysis demonstrated promising signals of both target engagement and molecular dose response among the 250mg and 500mg IR doses.

- Landos will be conducting a Phase 2 proof-of-concept clinical trial for NX-13, which will be dose ranging, blinded, placebo-controlled, and statistically powered.

- The Company is on track for first site activation and patient enrollment for the NX-13 Phase 2 trial in the second quarter of 2023. The Company expects to report topline data from the trial by the fourth quarter of 2024.

- In addition to UC, the Company believes NX-13 has the potential to treat CD.

Omilancor
Omilancor is a novel, oral, LANCL2 agonist in development for the once-daily treatment of UC.

- Landos has completed a global Phase 2 trial in mild-to-moderate UC, which confirmed the safety and tolerability characteristics observed in the Phase 1a trial. While this study showed a clinical remission rate of over 30%, it did not reach statistical significance due to a higher-than-expected placebo remission rate of over 20%.

- A pre-specified disease severity analysis, however indicated clinical efficacy in more severe UC patients, and that an enhanced formulation may further improve Omilancor efficacy in future trials.

- The Company is evaluating whether an enhanced formulation may improve absorption and local bioavailability of Omilancor to the colonic mucosa, and potentially increasing durable efficacy.

LABP-104
LABP-104 is a novel, oral, systemically distributed LANCL2 agonist in development for the once-daily treatment of SLE and/or RA.

- Today, Landos announced that it recently completed a successful Phase 1a clinical trial of LABP-104, which was well-tolerated in healthy volunteers and did not result in any serious adverse events.

- The Phase 1a clinical trial results for LABP-104 support its potential as a treatment for SLE and/or RA, and the Company is evaluating whether future formulations may provide enhanced absorption characteristics to maximize drug effects.

Pre-Clinical Programs

The Company also has four promising, novel pre-clinical programs in its portfolio, including:

- **LABP-66:** A novel NLRX1 agonist in development for the treatment of MS, Alzheimer's Disease, and other debilitating CNS diseases.
    - As announced in August 2021, Landos entered into a research collaboration with Dr. Peter Calabresi, Director of the Multiple Sclerosis Center and Professor of Neurology at Johns Hopkins University School of Medicine. The research is funded by the National Institute of Health and is focused on further validating the NLRX1 immunometabolic pathway in MS. Since inception, the study has progressed from in vitro analysis of the role of NLRX1 activation in glial cells to mouse studies to validate and expand the initial findings in preclinical models of MS. Dr. Calabresi's team recently presented their data at the National MS Society Tykeson Fellows Conference and the Race to Erase MS Symposium.

- **LABP-73:** A novel NLRX1 agonist in development for the treatment of Asthma and Chronic Obstructive Pulmonary Disease.

- **LABP-69:** A novel PLXCD2 agonist in development for the treatment of RA and Diabetic Nephropathy. LABP-69 aims to increase IL-10 secretion and down regulate pro-inflammatory signals and angiogenesis, supporting its potential as a novel therapy for RA and Diabetic Nephropathy.

- **LABP-111:** A novel LANCL2 agonist in development for the treatment of NASH and Diabetes.

Financial Update

Today, Landos also separately announced that it has secured a $16.7 million investment at market price, from its largest shareholder, Perceptive Advisors. With this additional funding, the Company expects to have sufficient cash, cash equivalents and marketable securities to fund its planned operations into the first half of 2025.

“We believe this successful financing underscores our shareholders’ confidence and excitement in our path forward and the significant value that we expect to deliver as we advance NX-13. We look forward to executing on our strategic plan, leveraging the strength of Landos’ assets to drive value for patients and shareholders alike,” said Mr. Oakes.

Consistent with its enhanced focus, the Company has actively reprioritized Landos’ key initiatives and taken steps to right-size its cost structure. The Company has realized substantial operating cost efficiencies over the past year. As the Company transitions from the clinical conduct and close-out activities of previous trials, to finalizing the design and launch of the new NX-13 trial, Landos expects its cash requirements to remain relatively constant in future periods.

Corporate Update Conference Call

The Company will host a live webcast to provide a comprehensive update on Landos’ clinical development plans at 8:00 AM ET today.

The webcast can be accessed through the Company’s investor relations website at https://ir.landosbiopharma.com/, or by dialing 800-225-9448 (Toll Free) or 203-518-9708 (International). For those who cannot listen to the live webcast, a replay will be made available on the Company’s investor relations website.

About Landos Biopharma
Landos Biopharma is a clinical stage biopharmaceutical company focused on the development of first-in-class therapeutics for patients with autoimmune disease. The Company’s mission is to create safer and more effective treatments that address the therapeutic gap in the current treatment paradigm.

Landos has a portfolio of three novel targets anchoring libraries of immunometabolic modulation pathways, including seven potentially first-in-class, once-daily therapies targeting 14 indications in the immunology space. This includes our three clinical stage programs: NX-13 for Ulcerative Colitis and Crohn’s Disease; Omilancor for Ulcerative Colitis, Crohn’s Disease and Eosinophilic Esophagitis; and LABP-104 for Systemic Lupus Erythematosus and Rheumatoid Arthritis

The Company is currently focused on advancing the clinical development of NX-13 in Ulcerative Colitis.

For more information, please visit www.landosbiopharma.com.

Cautionary Note on Forward-Looking Statements
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 and regulatory plans for its product candidates and other statements containing the words “anticipate”, “plan”, “expect”, “may”, “will”, “could”, “believe”, “look forward”, “potential”, the negatives thereof, variations thereon and similar expressions, or any 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, including the planned Phase 2 trial of NX-13, availability and timing of data from ongoing clinical trials, expectations regarding the reformulation for Omilancor, expectations for regulatory approvals, other matters that could affect the availability or commercial potential of the Company’s product candidates, the Company’s anticipated cash runway, potential partnering opportunities and other similar risks. Risks regarding the Company’s business are described in detail in its Securities and Exchange Commission (“SEC”) filings, including in its Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q, which are available on the SEC’s website at www.sec.gov. Additional information will be made available in other filings that the Company makes from time to time with the SEC. Such risks may be amplified by the impacts of the COVID-19 pandemic. 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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