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LIXTE Biotechnology Announces a Supported Collaborative Trial to Study LIXTE's First-in-Class PP2A Inhibitor, LB-100, Plus GSK's Immunotherapy, Dostarlimab, in Clear-Cell Ovarian Cancer

The Phase 1b Clinical Trial Focuses on Assessing the Safety and Efficacy of the Two-Drug Combination in a Cancer Associated with Longer Survival to Immunotherapy When Genetically Deficient in PP2A

PASADENA, CA, Sept. 20, 2023 (GLOBE NEWSWIRE) -- LIXTE Biotechnology Holdings, Inc. (Nasdaq: LIXT) ("LIXTE"), today announced a Phase 1b collaborative clinical trial to assess whether adding Lixte's LB-100 to GSK's programmed death receptor-1 (PD-1)-blocking monoclonal antibody, dostarlimab, may enhance the effectiveness of immunotherapy in the treatment of ovarian clear cell carcinoma (OCCC). The clinical trial is sponsored by The University of Texas - MD Anderson Cancer Center and will be conducted at MD Anderson and will also be open at Northwestern University's Robert H. Lurie Comprehensive Cancer Center. LIXTE will provide LB-100; GSK will provide dostarlimab and financial support for the clinical trial.

The clinical trial is based on the observation of longer survival of patients with OCCC treated with immunotherapy whose cancer cells have an acquired gene mutation resulting in a reduction in PP2A. This finding was reported by the lead clinical investigators of this new trial[1]: Amir Jazaeri MD, Professor of Gynecologic Oncology at MD Anderson, and Emily Hinchcliff, MD, MPH, Assistant Professor of Obstetrics and Gynecology at Northwestern University Feinberg School of Medicine. The observation by Drs. Jazaeri and Hinchcliff, that a genetically acquired reduction in PP2A enhances sensitivity to immunotherapy, raises the possibility that reducing PP2A pharmacologically with LB-100 will enhance the anti-tumor effect of the PD-1 blocking monoclonal antibody dostarlimab in patients with OCCC lacking the genetic reduction in PP2A.

John S. Kovach, M.D., LIXTE's founder and Chief Executive Officer, said, "Preclinical data supports the idea that LB-100 enhances the efficacy of PD-1 therapy.[1] Clinical data also

supports this idea, in that patients with ovarian clear cell carcinoma with dysfunctional PP2A due to somatic mutations in PPP2R1A have shown dramatically longer survival after treatment with immune checkpoint blockers."

Dr. Hinchcliff, said, "OCCC is a comparatively chemotherapy resistant disease and therefore has very limited options for treatment. This clinical trial is an exciting alternative approach that leverages the potential synergy between these two agents and is aiming to improve the impact immunotherapy may have for these patients."

About LIXTE Biotechnology Holdings, Inc.

LIXTE Biotechnology Holdings, Inc. is a clinical-stage pharmaceutical company focused on new targets for cancer drug development and developing and commercializing cancer therapies. LIXTE has achieved a breakthrough demonstrating that its first-in-class lead clinical PP2A inhibitor, LB-100, is well-tolerated in cancer patients at doses associated with anti-cancer activity. Based on extensive published preclinical data (see www.lixte.com), LB-100 has the potential to significantly improve outcomes for patients undergoing various chemotherapies or immunotherapies. LIXTE's new approach has no known competitors and is covered by a comprehensive patent portfolio. Initial proof-of-concept clinical trials are in progress.

Forward-Looking Statement Disclaimer

This announcement contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, and Section 21E of the Securities Exchange Act of 1934. For example, statements regarding the Company's financial position, business strategy and other plans and objectives for future operations, and assumptions and predictions about future activities, including the continuing development of proprietary compounds, the planning, funding, coordination and potential results of clinical trials, the patent and legal costs to protect and maintain the Company's intellectual property worldwide, and the Company's ability to obtain and maintain compliance with Nasdaq's continued listing requirements, are all forward-looking statements. These statements are generally accompanied by words such as "intend," anticipate," "believe," "estimate," "potential(ly)," "continue," "forecast," "predict," "plan," "may," "will," "could," "would," "should," "expect" or the negative of such terms or other comparable terminology.

The Company believes that the assumptions and expectations reflected in such forward-looking statements are reasonable, based on information available to it on the date hereof, but the Company cannot provide assurances that these assumptions and expectations will prove to have been correct or that the Company will take any action that the Company may presently be planning. However, these forward-looking statements are inherently subject to known and unknown risks and uncertainties. Actual results or experience may differ materially from those expected or anticipated in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, regulatory policies, available cash resources, research results, competition from other similar businesses, and market and general economic factors.

Readers are urged to read the risk factors set forth in the Company's filings with the United States Securities and Exchange Commission at https://www.sec.gov. The Company disclaims any intention or obligation to update or revise any forward-looking statements,

whether as a result of new information, future events or otherwise.

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[1] **Hinchcliff EM,** Patel A, Fellman B, Westin SN, Sood A, Soliman P, Shafer A, Meyer L, Fleming N, Bathala Y, Ganeshan D, Hwu P, Lu K, **Jazaeri A**. Loss-of-function mutations in PPP2R1A Correlate with Exceptional Survival in Ovarian Clear Cell Carcinomas Treated with Immune Checkpoint Inhibitors. National oral presentation at SGO Annual Meeting, March 2022

Source: Lixte Biotechnology Holdings, Inc.