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LIXTE Biotechnology and the Spanish Sarcoma Group Enroll First Patient in a Phase 1b/2 Randomized Trial of Doxorubicin +/- LIXTE's Lead Anti-Cancer Compound, LB-100, in Advanced Soft Tissue Sarcomas

PASADENA, CA, June 07, 2023 (GLOBE NEWSWIRE) -- LIXTE Biotechnology Holdings, Inc. (Nasdaq: LIXT) ("LIXTE"), a clinical-stage drug discovery company developing pharmacologically active drugs for use in cancer treatment, today announced the enrollment of the first patient in the Phase 1b portion of the Phase 1b/2 protocol (NCT05809830) to determine the appropriate dose of LB-100 given with a standard dose of doxorubicin. Once the dose is determined, a randomized Phase 2 study will be initiated seeking to gain evidence that the inclusion of doxorubicin increases time to a progression and/or overall survival of patients with advanced soft tissue sarcomas (ASTS).

John S. Kovach, MD, LIXTE's founder and Chief Executive Officer, commented, "The Phase 1b portion of the clinical trial to determine the recommended phase 2 dose (RP2D) is expected to be completed within approximately nine months from commencement. Subsequently, up to ten more clinical sites are expected to join the international Phase 2 portion of the study to enter up to 150 patients, randomized to standard cytotoxic chemotherapy with doxorubicin alone, versus doxorubicin plus LB-100. Given the lack of effective first-line treatments for ASTS, this trial has been designed to provide data expected to be sufficient to justify proceeding to a Phase 3 comparative study."

Dr. Javier Martin-Broto, sarcoma expert at the Fundación Jiménez Díaz University Hospital, Madrid, Spain, the principal investigator of the clinical trial, commented, "This clinical trial offers innovative research in the sarcoma field aiming to explore in the clinic a combination of doxorubicin and LB-100, an inhibitor of PP2A, which has proved to be synergistic in the preclinical setting. The Phase 1b part is starting now, while deep investigations are being developed to search the most robust predictive biomarkers for LB-100 activity in the sarcoma context. Investigators of this trial are excited and hopeful, with the idea of potentially improving the efficacy exhibited by doxorubicin alone during its solo 40-year reign. We have 3 activated sites in Spain right now and 3 additional sites will join the Phase 1b part in the coming weeks."

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.

About GEIS (Grupo Español de Investigación en Sarcomas)

GEIS is a non-profit organization in Spain engaged in the research, development and management of studies and clinical trials for sarcomas. GEIS has a mission to ensure the best healthcare to sarcoma patients by helping bring new treatments to them through clinical research. GEIS has successfully partnered with various institutions and companies to help bring new treatments to patients with sarcomas. Through the group's many research projects it has created or participated in over the years, it has made a significant impact in the global research effort to better treat patients with sarcomas. For more information: http://www.grupogeis.org.

Forward-Looking Statements

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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