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LIXTE Biotechnology Reports First Spanish Site Activated to Begin Accrual of Patients for a Phase 1b/2 Clinical Trial of LIXTE's Lead Anti-Cancer Compound, LB-100, Added to Doxorubicin as First-Line Treatment of Advanced Soft Tissue Sarcoma

First clinical trial seeking to determine if the potentiation of cytotoxic chemotherapy by LB-100 occurs in cancer patients as has been shown in multiple animal studies across a spectrum of cancers

PASADENA, CA, April 24, 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, announced that the Spanish Sarcoma Research Group (Grupo Español de Investigación en Sarcomas, or GEIS) completed its first site initiation visit in preparation for the advanced soft tissue sarcoma (ASTS) clinical trial at Fundación Jiménez Díaz University Hospital (Madrid).

Fundación Jiménez Díaz University Hospital is the home base of Dr. Javier Martín-Broto, Coordinating Investigator of the clinical trial, GEIS Co-Founder, and an internationally recognized expert in sarcoma research and therapy. Three additional GEIS-associated cancer research centers, located in Valencia, Barcelona, and Madrid, Spain, are expected to be activated in the near-term, with Phase 1b patient accrual planned to begin by mid-May 2023.

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.

John S. Kovach, MD, Founder and CEO of LIXTE, said, "We are very pleased to finally have an opportunity to test whether LB-100 improves the treatment of ASTS. GEIS has been very patient, having had to wait several months for various regulatory approvals to introduce LB-100 into a European clinical trial program. The fact that this trial design is still relevant attests to the slow pace of finding better treatments for this disease."

For a more complete description of the science underlying the study developed by Dr. Martín-Broto and his colleagues, please see:

LIXTE Biotechnology Announces Approval of a Phase 1b/2 Randomized Trial of Doxorubicin +/-Lb-100 in Advanced Soft Tissue Sarcomas to be Conducted by the Spanish Sarcoma Group

The Spanish Sarcoma Group Will Lead a European Consortium to Evaluate the Ability of Lixte Biotechnology Holdings' LB-100 to Improve First Line Therapy for Advanced Soft Tissue Sarcomas

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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