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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

EAST SETAUKET, NY, Aug. 06, 2019 (GLOBE NEWSWIRE) -- Lixte Biotechnology Holdings, Inc. ([OTCQB: LIXT](#)) announced that it signed a clinical trial agreement with the *Spanish Sarcoma Group (Grupo Español de Investigación en Sarcomas, GEIS)* to support a Phase 1b/randomized Phase 2 study of doxorubicin, the global standard for initial treatment of advanced soft tissue sarcomas (ASTS), versus doxorubicin plus LB-100.

Dr. John S. Kovach, CEO of Lixte, said, "We are pleased to support this investigator-initiated trial proposed by GEIS, a leader for many years in seeking improved therapies for ASTS. GEIS has a network of referral centers in Spain and across Europe that has an impressive track record of efficiently conducting innovative studies in ASTS. We believe GEIS and their EU collaborators are an excellent team to evaluate the potential benefit of adding Lixte's non-cytotoxic inhibitor of DNA damage repair to standard treatment for this challenging disease. The goal is to enter the first patient in the last quarter of this year and to complete enrollment of approximately 170 patients over two years."

Dr. Kovach continued, "Doxorubicin alone has been the mainstay of first line treatment of ASTS for over 40 years with little therapeutic gain from adding cytotoxic compounds to or substituting other cytotoxic compounds for doxorubicin. In animal models, LB-100, an inhibitor of protein phosphatase2A (PP2A), consistently enhances the antitumor activity of doxorubicin without apparent increases in toxicity and, in a Phase 1 clinical trial, LB-100 alone was associated with stabilization of an advanced chondrosarcoma and fibrosarcoma for 6 and 9 months, respectively, without toxicity. LB-100 potentiates the effectiveness of agents like doxorubicin by inhibiting repair chemotherapy -induced DNA damage. We are excited to learn if the combination of LB-100 and doxorubicin will finally advance the effectiveness of ASTS therapy."

Dr. Javier Martin-Broto, Coordinating Investigator of the trial and medical oncologist at Virgen del Rocío University Hospital (Seville) commented, "Although there has been an increase in overall survival in advanced sarcoma in recent years, this gain has not been accompanied by advances in first line therapy. Anthracyclines, and specifically doxorubicin, is still the standard initial treatment. The growing list of negative phase III trials indicates to us that sarcoma therapy is in crisis. It is true that sarcoma encompasses more than 60 different subtypes and, for some of them, substantial advances have emerged. But it is also true that the most frequent sarcoma subtypes desperately need a turning point. One promising topic of research is the combination of doxorubicin with drugs that are able to

impair the mechanisms of DNA repair. LB-100 has demonstrated synergistic action in *in vivo* preclinical mesenchymal tumors. GEIS will lead a European initiative to conduct a Phase I/randomized II trial exploring the combination of doxorubicin plus LB-100 in first line of advanced soft tissue sarcomas.”

About Lixte Biotechnology Holdings, Inc.

[Lixte](#) is a biotech company that identifies enzyme targets associated with serious common diseases and then designs novel compounds to attack those targets. Lixte's product pipeline is primarily focused on inhibitors of protein phosphatases, used alone and in combination with cytotoxic agents and immune checkpoint blockers.

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 product demand, supply, manufacturing, costs, marketing and pricing factors 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, research results, competition from other similar businesses, and market and general economic factors. This discussion should be read in conjunction with the Company's filings with the United States SEC at <http://www.sec.gov/edgar.shtml>.

Additional information on the Company is available at www.liخته.com.

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