June 2, 2021

Lixte Biotechnology and City of Hope Enroll First Patient in Phase 1b Trial of Lead Compound LB-100 for Treatment of Small Cell Lung Cancer

- ***Extensive preclinical data shows LB-100 increases t h e effectiveness of chemotherapy in animal models***
- ***Due to the aggressive progression of small cell lung cancer,it is possible that therapeutic benefit in patients may be seen in this early-stage clinical trial***

EAST SETAUKET, NY, June 02, 2021 (GLOBE NEWSWIRE) -- Lixte Biotechnology Holdings, Inc. (Nasdaq: LIXT), a clinical-stage drug discovery company developing pharmacologically active drugs for use in cancer treatment, today announced the enrollment of the first patient in a Phase 1b clinical trial with City of Hope, a world-renowned independent cancer research and treatment center. The trial will assess the combination of Lixte's first-in-class protein phosphatase 2A (PP2A) inhibitor LB-100 with a standard regimen for previously untreated, extensive stage-disease small cell lung cancer (ED-SCLC) (NCT04560972).

John S. Kovach, M.D., Lixte founder and chief executive officer, said, "In collaboration with City of Hope, we are eager to pursue our well-grounded rationale for adding LB-100 to a standard ED-SCLC regimen of carboplatin and etoposide chemotherapy plus atezolizumab to enhance effectiveness. In preclinical studies, the malignant cells of this uniformly fatal cancer are genetically sensitive to PP2A inhibition by a process termed synthetic lethality and the effectiveness of the standard regimen is enhanced by LB-100.

"Small cell lung cancer comprises approximately 15% of all lung cancers worldwide with about 30,000 new cases annually in the U.S.," Dr. Kovach continued. "The median survival of patients with this especially aggressive type of lung cancer, even with current 'best' therapy, is approximately nine months. Because of such rapid disease progression, the therapeutic benefit of adding LB-100 to the standard treatment may be seen early on in this Phase 1b clinical trial."

Ravi Salgia, M.D., Ph.D., City of Hope's Arthur & Rosalie Kaplan Chair in Medical Oncology, said, "We are hopeful that this trial testing a potentially more effective therapeutic combination could provide another treatment option for small cell lung cancer patients. It is a disease that is currently difficult to treat, particularly after a patient has relapsed, so more therapeutic options are needed."

About the Study

In the Phase 1b trial of LB-100 for the treatment of ED-SCLC, Lixte's lead compound will be

given in combination with carboplatin, etoposide and atezolizumab, an FDA approved but marginally effective regimen, in previously untreated ED-SCLC. The dose of LB-100 will be escalated with fixed doses of the 3-drug regimen to reach a recommended Phase 2 dose (RP2D). Patient entry will then be expanded so that a total of 12 patients will be evaluable at the RP2D to confirm its safety and to look for objective evidence of potential therapeutic activity as assessed by objective response rate, duration of overall response, progression-free-survival and overall survival. The study is open at City of Hope in Duarte, California.

About City of Hope

City of Hope is an independent biomedical research and treatment center for cancer, diabetes and other life-threatening diseases. Founded in 1913, City of Hope is a leader in bone marrow transplantation and immunotherapy such as CAR T cell therapy. City of Hope's translational research and personalized treatment protocols advance care throughout the world. Human synthetic insulin, monoclonal antibodies and numerous breakthrough cancer drugs are based on technology developed at the institution. AccessHope™, a wholly owned subsidiary, was launched in 2019 and is dedicated to serving employers and their health care partners by providing access to City of Hope's exceptional cancer expertise. A National Cancer Institute-designated comprehensive cancer center and a founding member of the National Comprehensive Cancer Network, City of Hope is ranked among the nation's "Best Hospitals" in cancer by U.S. News & World Report. Its main campus is located near Los Angeles, with additional locations throughout Southern California and in Arizona. For more information about City of Hope, follow us on Facebook, Twitter, YouTube or Instagram.

About Lixte Biotechnology Holdings, Inc.

Lixte Biotechnology Holdings, Inc. (Nasdaq: LIXT), is a clinical-stage pharmaceutical company dedicated to discovering drugs for more effective treatments for many forms of cancer and other serious common diseases. A major driver of cancer is defects in the switches that turn the biochemical pathways in cells on and off. Most cancer research over the past 30 years has focused on the "on" switches because the "off" switches, especially the master "off" switch protein phosphatase (PP2A), were believed to cause intolerable toxicity in patients. Lixte has achieved a breakthrough with its novel, first-in-class lead compound, PP2A inhibitor LB-100, by demonstrating that it is readily tolerated in cancer patients at doses associated with anti-cancer activity. This innovative approach encourages cancer cells, damaged by chemo or other cancer therapies, to continue to replicate before repairing the damage, leading to the more efficient death and elimination of those cells from the body. Lixte has partnered with top medical institutions and leading academic research centers to advance the clinical development of its compounds. The LB-100 compound, of which there are no competitors known to Lixte, is being tested in three clinical cancer treatment studies with others in planning. www.lixte.com

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 Securities and Exchange Commission at http://www.sec.gov/edgar.shtml.

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