August 3, 2021

LIXTE BIOTECHNOLOGY'S LB-100 ELICITS ANTI- TUMOR ACTIVITY IN SMALL LUNG CANCER MODELS BY UNIQUE MECHANISMS IN AN IMPORTANT PRE-CLINICAL STUDY

A Pre-Clinical Study Reports that LB-100 Potentiates Standard Therapy for Small Cell Lung Cancer Providing a Strong Rationale for a Clinical Trial of LB-100 in Small Cell Lung Cancer Recently Initiated at City of Hope.

Pasadena, CA, Aug. 03, 2021 (GLOBE NEWSWIRE) -- Lixte Biotechnology Holdings, Inc. (Nasdaq:LIXT) announced that its lead clinical compound, LB-100, a protein phosphatase 2A (PP2A) inhibitor, was reported to enhance the effectiveness of elements of standard therapy in models of small cell lung cancer (SCLC) (Mirzapoiazova el al., Molecular Cancer Therapeutics, online July 12, 2021).

Dr. Ravi Salgia, MD, PhD, Professor and Chair of the Department of Medical Oncology and Therapeutics Research and Arthur & Rosalie Kaplan Chair in Medical Oncology, City of Hope, is the corresponding author of the paper. He is also the principal investigator for a recently opened Phase 1b clinical trial (NCT04560972) for patients with previously untreated advanced small cell lung cancer, in which LB-100 is added to a standard regimen of carboplatin, etoposide, and atezolizumab.

The subject clinical trial is funded by Lixte Biotechnology. Lixte's CEO, John S. Kovach, MD, and an author on the preclinical study (which was not funded by Lixte), commented that "Dr. Salgia and his scientific collaborators have carried out extensive pre-clinical studies of abnormal molecular features of SCLC and the effects of LB-100 on components of a standard regimen for the treatment of this disease. They found multiple metabolic changes associated with cell death in these cancer cells when exposed to LB-100 alone and when combined with the drugs in this standard clinical regimen for this notoriously aggressive disease."

Kovach continued "LB-100 has been reported to increase the effectiveness of a number of anti-cancer drugs against several different types of human cancers without increasing toxicity

in animal models. Of note in the current preclinical study of SCLC cells is 1) that LB-100 increases the amount of carboplatin that enters the tumor cells without increasing toxicity, and 2) that LB-100 potentiates the action of the immune-blocker, atezolizumab."

These observations are of great interest to Lixte because, taken together, they not only constitute a strong rationale for the recently opened clinical trial of LB-100 plus chemo-immunotherapy in SCLC but they complement earlier preclinical observations that LB-100 can 1) reverse resistance of cancer cells (ovarian) to cisplatin, another widely used chemotherapy drug (Chang et al., Molecular Cancer Therapeutics, Nov. 5, 2014) 2), increase the entry of another important anti-cancer agent, doxorubicin, into liver cancer cells associated with increased antitumor activity (Bai et al, Molecular Cancer Therapeutics, Aug. 14, 2014) , and 3) enhance the effectiveness of immune-blockers against several types of cancers (Ho et al. Nature Comm., May 29, 2018). These observations raise the possibility that the addition of LB-100 may be a general way to enhance standard therapies for cancers for which better treatments are urgently needed. The present trial in SCLC is an initial step in testing that hypothesis.

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 chemotherapy 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. Additional information can be obtained at the Company's website at 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 sec.gov/edgar.shtml.

Lixte Contact:
info@lixte.com
General Phone: (631) 830-7092
Investor Phone: (888) 289-5533

Source: Lixte Biotechnology Holdings, Inc.