November 22, 2021

LIXTE BIOTECHNOLOGY HOLDINGS, INC. ANNOUNCES THAT ENROLLMENT HAS RESUMED IN NATIONAL CANCER INSTITUTE'S TRIAL TO DETERMINE ABILITY OF LIXTE COMPOUND LB-100 TO ENTER RECURRENT, MALIGNANT BRAIN TUMORS

PASADENA, CA, Nov. 22, 2021 (GLOBE NEWSWIRE) -- Lixte Biotechnology Holdings, Inc. (Nasdaq: LIXT) announced that the National Cancer Institute (NCI) has resumed enrolling patients into their pharmacologic study of the ability of Lixte's lead compound, LB-100, to enter the brain and penetrate recurrent, malignant brain tumors, in patients where surgical removal of their cancer is indicated. After enrolling two patients in the study, enrollment was suspended in 2020 due to COVID-19 restrictions. Those restrictions have now been lifted and patient recruitment has resumed (Clinical trials registry NCT03027388). Up to 20 patients may be enrolled to obtain 8 evaluable subjects. A two-stage design will be used. Five patients will be initially treated. If at least 1 of 5 demonstrates the presence of LB-100 in tumor tissue, 3 additional subjects will be enrolled. If at least 2 of the 8 patients demonstrate LB-100 in tumor tissue, the study will be considered significant providing further support for studying if the addition of LB-100 to standard treatment regimens for malignant brain tumors improves outcomes. This study is being conducted by the National Cancer Institute under a Cooperative Research and Development Agreement (CRADA) with Lixte.

As Dr. John S. Kovach, founder and CEO of Lixte previously noted, "Glioblastoma brain tumors (GBMs) are very challenging to treat. Radiation combined with the chemotherapeutic drug, temozolomide has been the mainstay of GBM therapy for decades with some further benefit gained by the addition of one or more anti-cancer drugs but without major advances in overall survival for most patients. In animal models of GBM, Lixte's novel protein phosphatase inhibitor, LB-100, enhances the effectiveness of radiation, temozolomide chemotherapy treatments and immunotherapy, raising the possibility that LB-100 may improve outcomes of standard GBM treatment in the clinic. Although LB-100 has proven safe in patients at doses associated with apparent anti-tumor activity against several human cancers arising outside the brain, the ability of LB-100 to penetrate tumor tissue arising in the brain is not known. Unfortunately, many drugs potentially useful for GBM treatment do not enter the brain in amounts necessary for anti-cancer action.

The NCI study is designed to determine the extent to which LB-100 enters recurrent GBMs and related brain tumors. Patients having surgery to remove one or more tumors will receive one dose of LB-100 prior to surgery and have blood and tumor tissue analyzed for the

amount of LB-100 present and to determine whether the cells in the tumors show the biochemical changes expected to be present if LB-100 reaches its molecular target. The initial goal is to obtain this vital pharmacologic data in up to eight patients. Thanks to the innovative design of the NCI study, data from so few patients should be sufficient to provide a sound rationale for conducting a larger clinical trial to determine the effectiveness of adding LB-100 to the standard treatment regimen for GBMs."

For patients interested in enrolling in this clinical study, please contact NCI's toll-free number 1-800-4-Cancer (1-800-422-6237) (TTY: 1-800-332-8615) and/or the Website: https://trials.cancer.gov

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 sec.gov/edgar.shtml.

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