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First Two Patients Enrolled in National Cancer Institute Trial of the Ability of Lixte Biotechnology's LB-100 to Enter Recurrent Malignant Brain Tumors

EAST SETAUKET, NY, Dec. 04, 2019 (GLOBE NEWSWIRE) -- Lixte Biotechnology Holdings, Inc. ([OTCQB: LIXT](#)) announced that the National Cancer Institute (NCI) has enrolled the first two patients of a planned eight patient pharmacologic study of the ability of its lead compound, LB-100, to enter the brain and penetrate recurrent brain tumors in patients where surgical removal of the cancers is indicated ([clinical trials registry NCT03027388](#)). This study is being conducted by NCI under a Cooperative Research and Development Agreement (CRADA) with Lixte.

Dr. John S. Kovach, CEO of Lixte, said, "Primary malignant brain tumors (gliomas) are very challenging to treat. Radiation combined with the chemotherapeutic drug, temozolomide has been the mainstay of therapy of the most aggressive gliomas (glioblastoma multiforme, GBM) 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 the majority of patients. In animal models of GBM, Lixte's novel protein phosphatase inhibitor, LB-100, enhances the effectiveness of both 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 malignant gliomas. 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 goal is to obtain 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 a 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 Web site: <https://trials.cancer.gov>.

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/or X-ray and immune checkpoint blockers.

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>.

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

Lixte Contact:
eforman@lixte.com
(631) 830-7092



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