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Lixte Biotechnology Holdings, Inc. Announces That Its Novel Protein Phosphatase 2A Inhibitor Is Associated With Stabilization Of Several Types Of Cancer Without Dose-Limiting Toxicity

EAST SETAUKET, N.Y., Nov. 6, 2015 /PRNewswire/ -- Lixte Biotechnology Holdings, Inc. (OTCQB: LIXT) announced today that in an ongoing Phase I trial its lead anti-cancer compound, LB-100, was associated with stabilization of a variety of advanced cancers that had been progressing despite extensive prior treatment. The results were presented at the AACR-NCI-EORTC Molecular Targets and Cancer Therapeutics Conference, Boston, on November 6. The authors were Vincent Chung, City of Hope, Duarte, CA; Donald Richards, Texas Oncology, Tyler, TX; Fadi Braiteh, Comprehensive Cancer Centers of Nevada, Las Vegas, NV; John S. Kovach, Lixte Biotechnology Holdings, Inc., East Setauket, NY; Aaron Scott Mansfield, Mayo Clinic, Rochester, MN.

A total of 21 patients received LB-100 for 3-consecutive days in 3-week cycles. Nine of these patients had stabilization of their disease without significant toxicity. One patient with pancreatic cancer received 14 cycles of LB-100 (42 weeks); one with thymoma, 9 cycles; one with testicular and one with carcinoid of the lung, 5 cycles; two with ovarian, 3 and 6 cycles; and one with NSCLC and one with duodenal cancer, 3 cycles. The average number of cycles received at the last four evaluable dose levels of LB-100 was 4.8 (14.4 weeks). In a study by Mansfield et al (2015 JCO 33[15] suppl:2567), the average number of cycles of a new drug in 51 NCI-sponsored Phase 1 trials conducted from 1994-2014 involving 1841 patients was 2.0 (6-8 weeks).

John S. Kovach M.D., founder and president of Lixte, said "Lixte interprets the results as showing that LB-100 has single agent activity in suppressing the growth of several types of cancer. What is highly encouraging is that stabilization of disease occurred in the absence of dose-limiting toxicity. In fact, most patients tolerated repeated doses without any ill-effects. As pre-clinical studies have shown that LB-100 potentiates the effectiveness of cytotoxic agents, we believe that LB-100 alone and in combination with standard anti-cancer drugs and/or radiation may offer new therapeutic options for a spectrum of neoplastic diseases."

About Lixte Biotechnology Holdings, Inc.

Lixte is a drug discovery company that uses biomarker technology to identify enzyme targets associated with serious common diseases and then design novel compounds to attack those targets. Lixte's product pipeline encompasses two major categories of compounds at various stages of pre-clinical and clinical development which the Company believes have broad therapeutic potential not only for cancer but for other debilitating and life-threatening diseases. Lixte's unique phosphatase inhibitor, LB-100, is in a Phase I clinical trial at two NCI

designated Comprehensive Cancer Centers and three US Oncology Research sites (see ClinicalTrials.gov: Identifier NCT01837667).

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.lixte.com.

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