

First-In-Human Assessment of LB-100, Lixte Biotechnology's Protein Phosphatase 2A Inhibitor, Published in Clinical Cancer Research

EAST SETAUKET, NY -- (Marketwired) -- 01/04/17 -- Lixte Biotechnology Holdings, Inc. (OTCQB: LIXT) announced the <u>publication</u> online of Phase 1 results of its novel anti-cancer compound in *Clinical Cancer Research*, entitled "Safety, tolerability, and preliminary activity of LB-100, an inhibitor of protein phosphatase 2A, in patients with relapsed solid tumors." (https://doi.org/10.1158/1078-0432.CCR-16-2299)

John S. Kovach, M.D., Founder and President of Lixte said "We are encouraged that ten (46.7%) of twenty-one patients receiving at least 2 cycles of LB-100, a small molecule inhibitor of protein phosphatase (PP2A), achieved stable disease without limiting toxicity for up to 15 cycles of therapy including one patient with pancreatic cancer who had a partial regression. PP2A has long been recognized as a potentially important cancer treatment target but its inhibition was thought to be too toxic for clinical use. This Phase 1 study demonstrates the safety and tolerability of PP2A inhibition in patients with refractory solid tumors."

Dr. Kovach continued "In numerous animal models of cancer, inhibition of PP2A by LB-100 enhanced the anti-tumor activity of standard chemotherapy drugs and radiation without significantly enhancing their toxicity by altering cell cycle regulation and the DNA-damage repair response pathways. The mechanism by which LB-100 *used alone* apparently inhibited the growth of a variety of cancers in patients in the recently completed Phase I trial is not clear but PP2A activity is reduced by mutation directly or indirectly in many cancer types rendering them vulnerable to pharmacologic inhibition of PP2A. The results reported in *Clinical Cancer Research* support further development of LB-100 alone and in combination with standard cytotoxic regimens for a broad spectrum of tumors."

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 that the Company believes have broad therapeutic potential not only for cancer but also for other debilitating and life-threatening diseases.

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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