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Lixte Biotechnology Holdings Announces Expansion Of Clinical Sites For Its Phase I Trial Of Its Lead Anti-Cancer Compound, LB-100

EAST SETAUKET, N.Y., Jan. 23, 2015 /PRNewswire/ -- Lixte Biotechnology Holdings, Inc. (OTCQB: LIXT), announced that the number of clinical sites where its Phase I trial of Lixte's lead compound, LB-100, is being conducted, has been expanded from 1 to 5 institutions.

John S. Kovach, M.D., the founder and President of Lixte, said that, "the initial trial was planned to be completed at a single site. Accrual of patients, however, was slower than projected. The recent addition of 4 more active clinical oncologic research sites has already enhanced the rate of accrual with patient entry at the 5th planned dose escalation to be completed this month. The original time-line for completion of both parts of this 2-part trial was June 30, 2015. The estimated time to completion of Part 1 of the trial, the determination of dose and safety of LB-100 alone (maximum tolerated dose (MTD)), is now projected to be the 2nd quarter of 2015 and completion of Part 2, determination of the MTD of LB-100 combined with docetaxel, the 2nd quarter of 2016. The estimated cost for completion of both Part 1 and 2 is \$2,615,000 versus the original projection of \$2,038,000. The ultimate cost may vary depending on such factors as the number and rate of accrual of patients. The increase in cost is for management of the study, predominantly the monitoring of the additional new sites over a longer period of time."

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 cancer trial (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 condensed consolidated financial statements and notes thereto in the Annual Report on Form 10-Q for September 30, 2014.

For additional information, please see: www.lixte.com.

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/lixte-biotechnology-holdings-announces-expansion-of-clinical-sites-for-its-phase-i-trial-of-its-lead-anti-cancer-compound-lb-100-300024760.html>

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