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Lixte Biotechnology's Lead Compound Reported To Be Active Against Hematologic Cancers In Pre-Clinical Studies

EAST SETAUKTET, N.Y., Feb. 25, 2015 /PRNewswire/ -- Lixte Biotechnology Holdings Inc. (OTCQB: LIXT), noted that two recent reports suggest that its lead anti-cancer compound LB-100 may have a role in the treatment of at least two hematological cancers.

Dr. John Kovach, founder and president of Lixte, said that "Lixte has been developing LB-100 for the treatment of solid tumors because this novel compound potentiates the therapeutic activity of chemotherapy and radiotherapy without significant increases in toxicity in several animal models. LB-100 is currently in Phase I clinical trial to determine the appropriate dose of the compound alone and in combination with docetaxel for subsequent investigation of the combination in docetaxel-sensitive tumors. The finding that LB-100 may have anti-cancer activity against leukemias and other hematologic disorders would significantly increase potential clinical applications."

Dr. Kovach continued, "Investigators at the Terry Fox Cancer Center, Vancouver, BC, reported at the American Society of Hematology in December 2014, that LB-100 and a lipid-soluble homolog of LB-100 (LB-102) are active against imatinib-naive and imatinib-resistant human chronic myelogenous leukemia cells (CML) (Lai et al (2014) Blood 124:(21)899). Since almost all CML patients have remission of their disease with imatinib treatment yet eventually relapse, a new drug active alone or with imatinib for the treatment of imatinib-resistant CML would be welcome. Also of potential relevance to the use of LB-100 in hematological diseases is a report by investigators at the Moffitt Cancer Center, Tampa, Florida, that inhibition of protein phosphatase 2A (PP2A) is the mechanism of action by which the Celgene drug lenalidomide exerts for its clinical benefit in del5q myelodysplastic syndrome (MDS). PP2A is the target of LB-100 and the Moffitt investigators speculate that a novel inhibitor of PP2A like LB-100 may be useful in the treatment of del5qMDS given alone or in combination with lenalidomide (Sallman et al (2014) Front Oncol. 4:264)."

Dr. Kovach concluded, "The primary goal of our current Phase I trial is to determine the maximum tolerable dose (MTD) of LB-100 in combination with docetaxel and then to test to

what extent LB-100 improves the efficacy of docetaxel against common solid tumors in Phase 2 trials. However we are currently completing determination of the MTD of LB-100 alone, a step required before combining LB-100 with escalating doses of docetaxel. The new pre-clinical data briefly summarized above suggest that LB-100 merits evaluation in del5qMDS and imatinib-resistant CML once the safety profile of LB-100 is established even as we proceed to evaluate LB-100 with docetaxel in solid 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 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/lixe-biotechnologys-lead-compound-reported-to-be-active-against-hematologic-cancers-in-pre-clinical-studies-300041098.html>

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