

May 1, 2012



# **Lixte Biotechnology Holdings Announces Submission of an IND to the FDA for Approval of a Clinical Trial of LB-100, a First-in-Class, Anti-Cancer Compound**

EAST SETAUKET, N.Y., May 1, 2012 /PRNewswire/ -- John S. Kovach, M.D., Chair, Board of Directors and CEO of Lixte Biotechnology Holdings, Inc. (LIXT.PK), announced the submission of an IND application to the Food and Drug Administration to conduct a Phase I trial of its lead, anti-cancer compound, LB-100.

Dr. Kovach said, "We believe that LB-100, a novel anti-cancer compound, prevents cancer cells from defending themselves against standard types of cancer treatments. In pre-clinical animal models of cancer, LB-100 inhibits cancer cell growth on its own but, more importantly, it significantly enhances the killing of cancer cells by several widely used anti-cancer drugs including Temozolomide, Doxorubicin, and Docetaxel as well as radiation. In the initial Phase I trial to be conducted at a nationally recognized comprehensive cancer center, LB-100 will be evaluated alone and in combination with a standard anti-cancer drug. We hope that the improved anti-cancer activity of LB-100 combined with conventional anti-cancer treatments in animal models is borne out in the clinic without undue toxicity. If so, we believe that regimens containing LB-100 will be associated with meaningful benefit to patients with a number of different types of cancer."

About Lixte Biotechnology Holdings, Inc.

Lixte is engaged in development of improved treatments for cancer. The company was created to capitalize on opportunities to develop low cost, specific and sensitive tests for the early detection of cancers. Over the past four years, however, Lixte has evolved into what is now primarily a cancer drug discovery company, using biomarker technology to identify vulnerable anti-cancer targets and then create novel compounds to attack those targets.

The Company is developing new treatments for several cancers for which better treatments are urgently needed. The initial focus was on the most aggressive type of brain cancer of adults and children but now includes other cancers including breast, pancreas, stomach, and melanomas and sarcomas.

## **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 Quarterly Report on Form 10K for the year ending December 31, 2011.

**For additional information, please see: [www.Lixte.com](http://www.Lixte.com)**

SOURCE Lixte Biotechnology Holdings, Inc.