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FDA Approves Lixte Biotechnology's IND to Conduct a Phase 1b/2 Trial of LB-100 in Patients with Myelodysplastic Syndrome at Moffitt Cancer Center

EAST SETAUKET, NY, Nov. 05, 2018 (GLOBE NEWSWIRE) -- Lixte Biotechnology Holdings, Inc. (OTCQB: LIXT) announced that the FDA approved its IND to conduct a Phase 1b/2 trial of the safety and therapeutic benefit of Lixte's lead clinical compound, LB-100, in patients with low and intermediate-1 risk myelodysplastic syndrome (MDS) who have failed or are intolerant of standard treatment. The study will be conducted at Moffitt Cancer Center, Tampa, FL.

Dr. John S. Kovach, founder and CEO of Lixte, said, "We are very pleased to receive approval to proceed with a study of the potential benefit of our lead protein phosphatase 2A inhibitor, LB-100, in the treatment of refractory MDS to be conducted by the team at Moffitt, long-time leaders in this field. Low and intermediate-1 risk MDS are often characterized by failure to produce normal amounts of red blood cells, so that patients with this syndrome require frequent blood transfusions. Reduction in the number of transfusions needed by these patients is one major goal of therapy, and provides a readily assessable parameter of therapeutic benefit within a few months of initiating treatment. At present, there is only one drug, Revlimid (Celgene), approved for one subtype of MDS."

About Lixte Biotechnology Holdings, Inc.

Lixte is a biotech company that identifies enzyme targets associated with serious common diseases and then designs novel compounds to attack those targets. Lixte's product pipeline is primarily focused on inhibitors of protein phosphatases, used alone and in combination with cytotoxic agents and immune checkpoint blockers.

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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