

## Lixte Biotechnology Files an IND with the FDA to Conduct a Phase 1b/2 Trial of LB-100 in Patients with Myelodysplastic Syndrome at Moffitt Cancer Center

EAST SETAUKET, NY, Oct. 09, 2018 (GLOBE NEWSWIRE) -- Lixte Biotechnology Holdings, Inc. (OTCQB: LIXT) announced that it has submitted an IND to the FDA 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 looking forward to learning whether the anti-tumor activity of LB-100 found in preclinical models of MDS will be seen in patients with this increasingly common cancer. We are especially pleased that the study will be conducted by the expert MDS team at Moffitt, long-time leaders in this field. MDS is a complex neoplastic disorder for which new effective treatments are needed urgently. At present, there is only one drug, Revlimid (Celgene), approved for one subtype of MDS."

## About Lixte Biotechnology Holdings, Inc.

<u>Lixte</u> 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 <a href="http://www.sec.gov/edgar.shtml">http://www.sec.gov/edgar.shtml</a>.

## Additional information on the Company is available at<u>www.lixte.com</u>.

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Source: Lixte Biotechnology Holdings, Inc.