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Lixte Biotechnology Announces a Clinical Trial Agreement with Moffitt Cancer Center to Initiate Phase 1b/2 Trial Evaluating the Safety and Efficacy of LB-100 in Treatment of Patients with Low or Intermediate-1 Risk Myelodysplastic Syndrome

EAST SETAUKET, NY, Aug. 21, 2018 (GLOBE NEWSWIRE) -- [Lixte Biotechnology Holdings, Inc.](#) (OTCQB: LIXT) announced that it has entered into a Clinical Trial Agreement and Exclusive License Agreement with [Moffitt Cancer Center](#) to conduct a Phase 1b/2 study of the safety and therapeutic benefit of Lixte's lead clinical compound, LB-100, in patients with myelodysplastic syndrome (MDS). The trial will enter low and intermediate-1 risk MDS patients, including those with del(5q) MDS who have failed or are intolerant of standard treatment.

Dr. John S. Kovach, founder and CEO of Lixte, said, "Certain cancers possessing unique genetic changes are vulnerable to inhibition of an enzyme, protein phosphatase 2A (PP2A), by LB-100. Among these is myelodysplastic syndrome (MDS), an increasingly common family of neoplastic diseases, especially in persons aged 65 and older. MDS is characterized by failure of the bone marrow often causing significant anemia and requiring frequent blood transfusions. In preclinical models of MDS, treatment with LB-100 inhibits the growth and/or induces the death of the abnormal blood cells. Cells of one variant of MDS, termed del(5q) MDS, are missing 50% of their PP2A activity rendering them sensitive to PP2A inhibition."

Currently there is only one drug, lenalidomide, approved for the treatment of del(5q) MDS, and virtually all patients become resistant to this therapy.

"We are excited to embark on the clinical investigation of LB-100 in lower-risk MDS patients. If LB-100 proves to be effective in the clinic, it could be an important addition to the limited treatment options for patients failing standard treatment," said [David Sallman](#), M.D., assistant member of Moffitt's Malignant Hematology Department.

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.

About Moffitt Cancer Center

[Moffitt](#) is dedicated to one lifesaving mission: to contribute to the prevention and cure of

cancer. The Tampa-based facility is one of only 49 [National Cancer Institute-designated Comprehensive Cancer Centers](#), a distinction that recognizes Moffitt's scientific excellence, multidisciplinary research, and robust training and education. Moffitt is a Top 10 cancer hospital and has been nationally ranked by [U.S. News & World Report](#) since 1999. Moffitt devotes more than 2 million square feet to research and patient care. Moffitt's expert nursing staff is recognized by the American Nurses Credentialing Center with Magnet[®] status, its highest distinction. With more than 6,000 team members, Moffitt has an economic impact in the state of \$2.1 billion. For more information, call 1-888-MOFFITT (1-888-663-3488), visit [MOFFITT.org](#), and follow the momentum on [Facebook](#), [Twitter](#) and [YouTube](#).

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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