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LIXTE Biotechnology Holdings announces collaboration on a New Colon Cancer Clinical Trial

Clinical trial to test recent findings that show LIXTE's lead clinical compound, LB-100, increases recognition of colon cancer cells by the immune system

PASADENA, CA, June 14, 2024 (GLOBE NEWSWIRE) -- LIXTE Biotechnology Holdings, Inc. ("LIXTE" or the "Company") (Nasdaq: LIXT and LIXTW), a clinical stage pharmaceutical company, today announced a collaboration with Roche and the Netherlands Cancer Institute (NKI) to conduct a new clinical trial in immune therapy unresponsive (MSI Low) metastatic colon cancer.

As part of the new clinical trial, listed asNCT06012734 at clinicaltrials.gov, LIXTE will provide its lead compound, LB-100, and Roche will provide atezolizumab (Tecentriq®, a PD-L1 inhibitor) through the imCORE Network, an academic-industry collaboration that aims to accelerate cancer immunotherapy research through institution-sponsored studies.

"This is an exciting new clinical trial," said Neeltje Steeghs, M.D., Ph.D., medical oncologist from NKI and Antoni van Leeuwenhoek Hospital, who is serving as principal investigator of the trial. "Only about 15% of colon cancers are responsive to immunotherapy, the so-called MSI High cancers. However, approximately 85% of colon cancers are MSI Low where immunotherapy has no activity at all. If we are able to sensitize these tumors to immunotherapy with LB-100, we could bring immunotherapy as an effective treatment option to a large group of colon cancer patients."

Bas van der Baan, LIXTE's Chief Executive Officer, said, "The ongoing interest in and support of this clinical trial underscores the strength of the scientific rationale and potential of our lead compound, LB-100. This is the second recent clinical trial combining LB-100 with immunotherapy that is supported by a major pharmaceutical company, following the start of a clinical trial earlier this year that is being funded by GSK for the treatment of clear cell ovarian cancer."

NKI is one of the world's leading comprehensive cancer centers. René Bernards, Ph.D., a leader in the field of molecular carcinogenesis and Senior Staff Scientist at the Netherlands

Cancer Institute, is a member of LIXTE's Board of Directors.

A recent publication of new pre-clinical data in the journal *EMBO Reports* showed that LIXTE's lead compound, LB-100, can turn immunologically "cold" tumors "hot," thereby potentially enhancing the response to immunotherapy. This publication builds on a large body of scientific and emerging clinical evidence that LB-100 has strong synergy with checkpoint immunotherapy.

Tecentriq® (atezolizumab) is a registered trademark of Genentech, a member of the Roche Group.

About LIXTE Biotechnology Holdings, Inc.

LIXTE Biotechnology Holdings, Inc. is a clinical-stage pharmaceutical company focused on new targets for cancer drug development and developing and commercializing cancer therapies. LIXTE has demonstrated that its first-in-class lead clinical PP2A inhibitor, LB-100, is well-tolerated in cancer patients at doses associated with anti-cancer activity. Based on extensive published preclinical data (see www.lixte.com), LB-100 has the potential to significantly enhance chemotherapies and immunotherapies and improve outcomes for patients with cancer.

LIXTE's lead compound, LB-100, is part of a pioneering effort in an entirely new field of cancer biology – activation lethality – that is advancing a new treatment paradigm. LIXTE's new approach is covered by a comprehensive patent portfolio. Proof-of-concept clinical trials are currently in progress for colon, small cell lung and sarcoma cancers. Additional information about LIXTE can be found at www.lixte.com.

Forward-Looking Statement Disclaimer

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 activities, including the continuing development of proprietary compounds, the planning, funding, coordination and potential results of clinical trials, the patent and legal costs to protect and maintain the Company's intellectual property worldwide, and the Company's ability to obtain and maintain compliance with Nasdaq's continued listing requirements, 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 resources, research results, competition from other similar businesses, and market and general economic factors.

Readers are urged to read the risk factors set forth in the Company's filings with the United States Securities and Exchange Commission at https://www.sec.gov. The Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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