

# XBiotech In-licenses Anti-NY-ESO-1 Antibody Targeting Advanced Cancer

# April 2, 2018

# Agreement Centers on XBiotech's Proprietary Manufacturing Technology to Advance Anti-NY-ESO-1 Antibody 12D7

AUSTIN, Texas, April 02, 2018 (GLOBE NEWSWIRE) -- XBiotech USA, Inc. (NASDAQ:XBIT) announced today that it has obtained an exclusive, worldwide license from CT Atlantic AG (CTA), a Swiss biotechnology company. Under the terms of the license agreement, XBiotech will use its proprietary manufacturing technology to advance the development of the True Human<sup>TM</sup> anti-NY-ESO-1 monoclonal antibody, 12D7. Accordingly, XBiotech will now begin to establish the production capability to enable 12D7 clinical development.

The 12D7 antibody targets NY-ESO-1, a cancer-related protein commonly found in many kinds of aggressive tumors. The therapeutic use of 12D7 offers the potential to target advanced tumors by activating cellular immunity or antibody directed immune responses against tumors. A 12D7 therapy may be combined with other therapies that unleash the immune system to produce anti-cancer responses.

John Simard, President & CEO of XBiotech, commented, "The 12D7 antibody was isolated from a human immune response against cancer and is therefore a logical fit with our pipeline of human-derived antibodies. 12D7 offers the potential to be used as a therapy with minimal side effects—and safely in combinations with other agents, including checkpoint inhibitors—to help direct a patient's immune response against their cancer."

Simard further commented, "Although NY-ESO-1 has been the subject of an enormous amount of scientific investigation, pointing to its association with tumors and anti-tumor immunity, the 12D7 antibody has yet to be evaluated in clinical trials. 12D7 is a good example of how our unique manufacturing technology can be used to help advance promising candidates discovered elsewhere."

Prof. Alex Knuth, M.D., member of the Board of Directors at CTA, Medical Director and Chief Executive Officer of the National Center for Cancer Care and Research (NCCCR) and Chairman of Cancer Services at Hamad Medical Corporation, commented, "I am excited to bring this NY-ESO-1 specific True Human antibody to the clinic with the advanced technologies and expert guidance of XBiotech. NY-ESO-1 is the most immunogenic human cancer antigen known to date. The 12D7 antibody comes from a melanoma patient with a remarkably favourable disease course despite advanced metastasis. NY-ESO-1 immunity appears to predict a better response to immune checkpoint interventions and the 12D7 antibody has been shown to support conventional treatments like chemotherapy with better outcomes in animal models; and in combination with radiotherapy, 12D7 may also amplify immune responses against cancer cells."

### About 12D7 Antibody

Work from the laboratories of Dr. Alexander Knuth and Dr. Steve Rosenberg previously showed that cellular immunity against NY-ESO-1 can be activated in cancer patients. The 12D7 antibody is expected to target the NY-ESO-1 antigen directly, as well as work to help direct the patient's cellular immune response against NY-ESO-1 bearing tumors. 12D7 is the first True Human monoclonal antibody targeting NY-ESO-1.

NY-ESO-1 was discovered by researchers at the Ludwig Institute for Cancer Research and Weill Medical College of Cornell University in New York. Interestingly, NY-ESO-1 is encoded by the sex-linked X chromosome and is deregulated and expressed in a number of forms of cancer. NY-ESO-1 function is still not fully understood but may be involved in cell division in cancer. Consequently, expression of NY-ESO-1 is found in a wide range of metastatic tumors, including about 33% of all cancers of the bladder, esophagus, gut, liver, lung, ovaries, prostate and skin.

Natural antibody immunity against NY-ESO-1 is often seen in cancer patients but is absent in healthy individuals. The natural antibody 12D7 is thought to be capable of initiating cellular immune responses, a disease fighting mechanism that is now widely mobilized to fight cancer through the use of check point inhibitors.

The target of the 12D7 antibody, NY-ESO-1, is commonly found in high-grade malignancies. The therapeutic use of 12D7 may therefore offer the potential to target these aggressive tumors in part by activating cellular immunity or antibody directed immune responses to the site of tumors. Anti-NY-ESO-1 antibody therapy may benefit from being combined with other therapies that reduce immune suppression. These combination therapies in particular offer hope that 12D7 could be a breakthrough approach to unleashing anti-cancer immunity against many forms of cancer.

#### About True Human <sup>™</sup> Therapeutic Antibodies

Unlike previous generations of antibody therapies, XBiotech's True Human<sup>™</sup> antibodies are derived without modification from individuals who possess natural immunity to certain diseases. With discovery and clinical programs across multiple disease areas, XBiotech's True Human antibodies have the potential to harness the body's natural immunity to fight disease with increased safety, efficacy and tolerability.

# About XBiotech

XBiotech is a fully integrated global biosciences company dedicated to pioneering the discovery, development and commercialization of therapeutic antibodies based on its True Human<sup>™</sup> proprietary technologyXBiotech currently is advancing a robust pipeline of antibody therapies to redefine the standards of care in oncology, inflammatory conditions and infectious diseases. Headquartered in Austin, Texas, XBiotech also is leading the development of innovative biotech manufacturing technologies designed to more rapidly, cost-effectively and flexibly produce new therapies urgently needed by patients worldwide. For more information, visit www.xbiotech.com.

### **Cautionary Note on Forward-Looking Statements**

This press release contains forward-looking statements, including declarations regarding management's beliefs and expectations that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "would," "could," "expects," "plans," "contemplate," "anticipates," "believes," "estimates," "predicts," "projects," "intend" or "continue" or the negative of such

terms or other comparable terminology, although not all forward-looking statements contain these identifying words. Forward-looking statements are subject to inherent risks and uncertainties in predicting future results and conditions that could cause the actual results to differ materially from those projected in these forward-looking statements. These risks and uncertainties are subject to the disclosures set forth in the "Risk Factors" section of certain of our SEC filings. Forward-looking statements are not guarantees of future performance, and our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate, may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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