

XBiotech Announces First Patient in Study Evaluating MABp1 in Combination with Onivyde® and 5-fluorouracil/folinic acid for the Treatment of Pancreatic Cancer

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AUSTIN, Texas, Oct. 18, 2017 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT) announced today enrollment of the first patient into a Phase I single arm study evaluating the maximum tolerated dose of Onivyde[®] (Irinotecan liposome injection) and 5-fluorouracil/folinic acid in combination with MABp1 in a cohort of patients with advanced pancreatic adenocarcinoma and cachexia. The patient has begun treatment at Cedars-Sinai Medical Center under the care of Dr. Andrew Hendifar, the Study's Principle Investigator, Medical Oncology lead for the Gastrointestinal Disease Research Group and Co-Director of Pancreas Oncology at Cedars-Sinai. A total of 16 patients are expected to be enrolled in the study.

Dr. Hendifar commented, "We are excited to enroll our first patient in this novel combinatorial therapy for the treatment of advanced pancreatic cancer and cachexia. This is the first attempt to add an anti-inflammatory therapy to standard chemotherapy in an effort to improve the performance, quality of life, and survival in patients with this disease."

The study will also assess overall and progression free survival as well as evaluate the relationship between treatment tolerance and patient functional status. Various secondary measures, including changes in lean body mass, weight stability and levels of systemic inflammation will also be monitored. Onivyde will be given intravenously with MABp1 and 5-fluorouraci//folinic acid every two weeks until disease progression.

The prognosis for advanced pancreatic cancer remains poor despite decades of studies [1]. The 5-year survival has remained close to 5%, unchanged despite improvements in chemotherapeutics, surgical outcomes, and diagnostic techniques [1, 2]. Other than multi-agent cytotoxic therapy there have been no treatment advances for pancreatic cancer or its associated cachexia.

MABp1 was found to improve clusters of symptoms that included reduced pain, fatigue, improved appetite and increased lean body mass in advanced cancer patients. Patients that had these improvements were found to have less tumor progression, substantial reduced serious adverse events related to disease, and about a three-fold improvement in survival [3].

About True Human[™] Therapeutic Antibodies

XBiotech's True Human[™] 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[™] 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 <u>www.xbiotech.com</u>.

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," "vould," "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 whether as a result of new information, future events or otherwise, after the date of this press release.

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- 1. Li, D., et al., Pancreatic cancer. Lancet, 2004. 363(9414): p. 1049-57.
- 2. Panagiotarakou, M., et al., Use of supportive care for symptom management in pancreatic cancer: application of clinical research to patient care. Jop, 2012. **13**(4): p. 342-4.
- 3. Hickish T., et al., *MABp1* as a novel antibody treatment for advanced colorectal cancer: a randomised, doubleblind, placebo-controlled, phase 3 study. Lancet Oncol. 2017 Feb;18(2):192-201.



XBiotech Inc.