



XBiotech Announces Enrollment Completion, Positive Findings for Bermekimab in Pancreatic Cancer Study

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XBiotech and Cedars-Sinai Medical Center Evaluate Bermekimab in Combination with Chemotherapy in Patients with Pancreatic Cancer and Cachexia

AUSTIN, Texas, May 02, 2019 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ: XBIT) announced today enrollment of the final patient into its Phase I study¹ evaluating bermekimab in patients with advanced pancreatic adenocarcinoma and cachexia. The study is being conducted and led by principal investigator Andrew Hendifar, M.D., Medical Oncology lead for the Gastrointestinal Disease Research Group and Co-Director of Pancreas Oncology at Cedars-Sinai Medical Center². A total of 18 patients are enrolled in the study.

¹[NCT03207724](#)

² This research was partially supported through an external research grant from the US marketer of the chemotherapy product.

The purpose of the study is to assess the safety and tolerability of bermekimab in combination with chemotherapy. The study will also assess progression-free survival and overall survival of patients, as well as evaluate the relationship between treatment tolerance and patient functional status. Various health-related secondary measures, including changes in lean body mass, weight stability, and levels of systemic inflammation are also being assessed. Chemotherapy is being given intravenously with bermekimab every two weeks until disease progression. Extensive historical data on the pancreatic cancer population will be used to evaluate secondary endpoints in this study.

Dr. Hendifar commented, "We have seen excellent tolerability with bermekimab in combination with the chemotherapy regimen. Therapeutic activity and patient outcomes appear to be favorable when compared to similar pancreatic cancer patient populations refractory to therapy."

John Simard, President & CEO of XBiotech, said, "This is our first combination therapy for bermekimab and we are very happy to see this regimen may improve the tolerability and efficacy of treatment for pancreatic cancer patients. We are grateful to Cedars-Sinai, Dr. Hendifar, and especially the courageous patients for participating in the study."

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. Bermekimab was found to improve clusters of symptoms and led to improvements such as reduced pain and fatigue, improved appetite, and increased lean body mass in advanced cancer patients. Patients who had these improvements were found to have less tumor progression, substantially reduced serious adverse events related to disease, and approximately 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 technology. XBiotech 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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- [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, double-blind, placebo-controlled, phase 3 study*. [Lancet Oncol](#). 2017 Feb;18(2):192-201.



Source: XBiotech Inc.