XBiotech Announces Agreement with Cedars-Sinai Medical Center to Evaluate MABp1 in Combination with Onivyde® and 5-fluorouracil/folinic acid for the Treatment of Pancreatic Cancer

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AUSTIN, Texas, Sept. 20, 2017 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT) announced today its agreement with Cedars-Sinai Medical Center located in Los Angeles, California, whereby XBiotech will provide its interleukin-1 alpha antagonist, MABp1, for 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 study will also assess efficacy using various secondary measures including changes in lean body mass, weight stability, IL-6 levels, overall and progression free survival as well as evaluation of the relationship between treatment tolerance and patient functional status.

Andrew Hendifar, M.D., Medical Oncology lead for the Gastrointestinal Disease Research Group at Cedars-Sinai and Co-Director of Pancreas Oncology, will be leading the study which is planned to enroll a total of 16 patients at the Cedars-Sinai Medical Center. Onivyde will be given intravenously with MABp1 and 5-fluorouracil/folinic acid every two weeks until disease progression.

Dr. Hendifar commented, “The results to date with treatment of MABp1 show much promise as an effective therapy in this setting. I look forward to evaluating this combination therapy to determine its safety and clinical benefit.”

Despite decades of clinical trials, the prognosis for advanced pancreatic cancer is poor [1]. The 5-year survival has remained close to 5% and unchanged despite improvements in chemotherapeutics, surgical outcomes, and diagnostic techniques [1, 2]. Advanced pancreatic adenocarcinoma is characterized by progressive weight loss and nutritional deterioration [3]. It is estimated that up to 80% of these patients present with cachexia [4]. This syndrome has been linked not only to survival, but also to alterations in host defenses, functional ability, and quality of life. In a Phase III clinical study, MABp1 was found to improve clusters of symptoms that included reduced pain, fatigue, improved appetite and increased lean body mass. Patients that had these improvements were found to have reduced disease progression and serious adverse events, and about a three-fold improvement in survival.

Other than multi-agent cytotoxic therapy there have been no treatment advances for pancreatic cancer or its associated cachexia. Despite the availability of effective chemotherapy, only between 15-40% of pancreatic cancer patients are able to receive second line treatment. Importantly, cachexia and its associated fatigue and deconditioning, may explain the difficulty in providing continued therapy after progression in the first-line. It is hoped that MABp1 used in combination with Onivyde will help control disease, reduce symptoms and allow patients to receive treatment longer, thereby improving outcomes.

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 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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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. Splinter, T.A., *Cachexia and cancer: a clinician's view.* Ann Oncol, 1992. **3 Suppl 3**: p. 25-7.
4. Ryan, D.P. and M.L. Grossbard, *Pancreatic Cancer: Local Success and Distant Failure.* Oncologist, 1998. **3**(3): p. 178-188.

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