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# **MabVax Therapeutics Files Investigational New Drug Application for Novel Radioimmunotherapy Agent MVT-1075**

**MVT-1075 Combines the Company's HuMab-5B1 Antibody with the Radiopharmaceutical ( $^{177}$ )Lutetium to Treat Pancreatic Cancer. Patient Enrollment in Trial Expected to Begin in Early 2017**

SAN DIEGO, Jan. 9, 2017 /PRNewswire/ -- [MabVax Therapeutics Holdings, Inc.](#) (Nasdaq: MBVX), a clinical-stage oncology drug development company, announces the filing an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for MVT-1075 ( $^{177}\text{Lu-CHX-A}''\text{-DTPA-HuMab5B1}$ ), the Company's novel fully human antibody radioimmunotherapy (RIT). Subject to receiving FDA authorization to proceed, MabVax plans to initiate the phase I clinical trial in patients with recurrent pancreatic cancer and other CA19-9 positive malignancies early in 2017. This is the third IND filed by MabVax that builds on the tumor targeting characteristics of the HuMab-5B1 antibody discovered from immune responses of cancer patients vaccinated with the Company's proprietary cancer vaccines.

The MVT-1075 RIT agent combines the targeting specificity of the HuMab-5B1 antibody for an antigen overexpressed on pancreatic cancer and other CA19-9 positive cancers with  $^{177}\text{Lutetium}$  to target delivery of therapeutic radiation to cancer cells. Preclinical studies have demonstrated marked suppression and in some instances regression in xenograft animal models of pancreatic cancer, potentially making it an important new therapeutic agent in the treatment of pancreatic cancer and other cancers expressing the same antigen, CA19-9.

In this initial phase I trial the Company plans to evaluate the safety, dosimetry, and pharmacokinetics of MVT-1075. Patients enrolled in the study will have been diagnosed with recurrent locally advanced or metastatic pancreatic ductal adenocarcinoma (PDAC) or other CA19-9 positive malignancies. Patient disease status will be evaluated based on tumor measurements using RECIST 1.1 criteria. The investigative sites will include Memorial Sloan Kettering Cancer Center in New York City.

In November 2016, MabVax reported positive interim results from two phase I trials. The

first trial is evaluating the Company's therapeutic antibody MVT-5873, in which safety was reported to have been established at three incremental dose levels by treating 16 patients at three clinical sites. Patients continue to be recruited to establish the recommended phase II dose (RP2D). The second trial is evaluating the Company's Immuno-PET diagnostic agent MVT-2163. The Company reported that phase I trial results demonstrated acceptable interim safety, pharmacokinetics, and biodistribution in the initial two cohorts of patients: the first cohort was administered MVT-2163 alone; and the second cohort was given MVT-2163 following administration of MVT-5873. Target specificity was demonstrated by correlation with lesions identified by conventional computerized tomography (CT) scans and patients are actively being recruited to this trial.

David Hansen, MabVax's President and Chief Executive Officer, said, "Following the positive interim data readout from our two ongoing phase I trials, we are excited to take this next step forward in our development strategy. Subject to receiving FDA authorization to proceed, we plan on expanding the HuMab-5B1 program to include delivery of a potent new radiotherapy agent. We are hopeful that this approach will provide a new treatment option for these difficult-to-treat cancers."

#### **About MabVax:**

MabVax Therapeutics Holdings, Inc. is a clinical-stage biotechnology company focused on the development of antibody-based products to address unmet medical needs in the treatment of cancer. MabVax has discovered a pipeline of human monoclonal antibody products based on the protective immune responses generated by patients who have been immunized against targeted cancers with the Company's proprietary vaccines. MabVax also has the exclusive license to the therapeutic vaccines from Memorial Sloan Kettering Cancer Center. Additional information is available at [www.mabvax.com](http://www.mabvax.com).

#### **Forward Looking Statements:**

This press release contains "forward-looking statements" regarding matters that are not historical facts, including statements relating to the Company's clinical trials of MVT-1075, MVT-5873, and MVT-2163. We have no assurance that any of the three product candidates will be fully developed by the Company. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "anticipates," "plans," "expects," "intends," "will," "potential," "hope" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon current expectations of the Company and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties. Detailed information regarding factors that may cause actual results to differ materially from the results expressed or implied by statements in this press release relating to the Company may be found in the Company's periodic filings with the Securities and Exchange Commission, including the factors described in the section entitled "Risk Factors" in its annual report on Form 10-K for the fiscal year ended December 31, 2015, as amended and supplemented from time to time and the Company's Quarter Reports on Form 10-Q and other filings submitted by the Company to the SEC, copies of which may be obtained from the SEC's website at [www.sec.gov](http://www.sec.gov). The parties do not undertake any

obligation to update forward-looking statements contained in this press release.

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