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MabVax Therapeutics Reports Interim Safety and Imaging Results from Phase I Clinical Trials in HuMab-5B1 Antibody Development Programs

Sufficient safety established to initiate the evaluation of MVT-5873 as a front-line therapy in combination with a standard of care chemotherapy

Safety and proof of concept demonstrated for tumor visualization with MVT-2163. Advancing to optimize image in pancreatic cancer patients.

SAN DIEGO, Nov. 14, 2016 /PRNewswire/ -- MabVax Therapeutics Holdings, Inc. (NASDAQ: MBVX), a clinical stage immuno-oncology drug development company, reported on progress from its two HuMab-5B1 antibody phase I programs evaluating the use of MVT-5873 as a therapeutic antibody and MVT-2163 as an immuno-PET imaging agent in patients with locally advanced and metastatic pancreatic cancer or other CA19-9 positive malignancies.

MVT-5873 Interim Phase I Data in Pancreatic Cancer

The MVT-5873 phase I clinical trial initiated in February 2016 is designed to establish safety and determine the recommended phase II dose (RP2D) for MVT-5873 as both as monotherapy (Part 1 of the trial), and in combination with standard of care chemotherapy (Part 2) using nab-paclitaxel plus gemcitabine. Initiation of Part 2 requires establishing three safe dose levels for MVT-5873 as monotherapy in patients with relapsed or refractory locally advanced or metastatic pancreatic cancer. The Company reports that the safety of MVT-5873 has been established at three incremental dose levels by treating 16 patients at three clinical sites. While patients continue to be recruited to establish the RP2D, the Company also reports that Part 2 of the clinical trial is now open and will include patients with previously untreated pancreatic cancer receiving a standard of care chemotherapy as defined in the protocol.

To date, the study has consented 28 subjects with 3 in screening, 9 screen failures, and 16 subjects treated. Of the 16 patients treated, six continue to receive treatment. Patients can remain on therapy based on dose tolerability and investigator assessment of

continued benefit including assessment of disease status using RECIST 1.1 criteria to evaluate tumor response rate and duration of response. Stable disease was noted for seven patients lasting from three months to eight months. The dosage safety levels established in Part 1 of the trial also support the dosage levels of MVT-5873 to be used in conjunction with the company's MVT-2163 immuno-PET imaging agent and the MVT-1075 radioimmunotherapy product which is planned to begin phase I clinical evaluation early in 2017.

MVT-2163 Interim Phase I Data in Pancreatic Cancer

The MVT-2163 phase I trial was initiated in June of this year to evaluate the company's next generation diagnostic PET imaging agent in patients with locally advanced or metastatic adenocarcinoma of the pancreas (PDAC) or other CA19-9 positive malignancies. MVT-2163 (^{89}Zr-HuMab-5B1) combines the well-established PET imaging radiolabel Zirconium [^{89}Zr] with the targeting specificity of MVT-5873. This trial is designed to establish safety, pharmacokinetics, biodistribution, and the amount of MVT-5873 to be used in co-administration to obtain optimized PET scan images. The company has demonstrated interim safety, pharmacokinetics, and biodistribution by completing the initial two cohorts of patients: the first cohort administered MVT-2163 alone and the second cohort administered MVT-2163 following a blocking dose of MVT-5873. The company reports that the initial PET images demonstrated target specificity by correlation with lesions identified by conventional computerized tomography (CT) scans. The biodistribution data obtained in the first two cohorts demonstrates improvement in PET images by pre-administration of MVT-5873, as has been observed with other antibody based PET agents. The company is actively recruiting patients and expects to establish the optimal co-administration dose of MVT-5873 early in 2017.

"Our strategy at the outset was to initiate these two clinical trials concurrently to address the key questions of safety and targeting specificity for the HuMab-5B1 antibody. We are highly encouraged by these promising early results from the MVT-5873 and MVT-2163 clinical trials," stated President and CEO J. David Hansen. He added, "We are moving ahead with the planned combination of MVT-5873 with a standard of care chemotherapy in a chemotherapy-naïve pancreatic cancer patient population and are looking forward to presenting these results next year. We are continuing to accrue patients in order to establish the RP2D for MVT-5873 as a monotherapy. In the MVT-2163 trial, dose escalation continues to confirm optimal dose and timing for the best PET scan image. Finally, the company remains on track for submitting the Investigational New Drug Application (IND) for MVT-1075 to the Food And Drug Administration (FDA) later this year, and plans to initiate the phase I trial of MVT-1075 in the first half of 2017 after receiving FDA authorization to proceed."

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 vaccinated against targeted cancers with the Company's proprietary vaccines.

MabVax's HuMab-5B1 antibody is fully human and was discovered from the immune response of cancer patients vaccinated with an antigen-specific vaccine during a Phase I trial at Memorial Sloan Kettering Cancer Center. The antigen the antibody targets is expressed on more than 90% of pancreatic cancers, making the antibody potentially broadly applicable to most patients suffering from this type of cancer. Additional information is available at 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 progress in its two phase I clinical trials of MVT-5873 and MVT-2163, and plans for 2017. We have no assurance that all of the product development pipeline 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, and the Company's Quarterly Reports on Form 10-Q, as such filings may be amended and supplemented from time to time, and other filings and reports by the Company with the SEC, copies of which may be obtained from the SEC's website at www.sec.gov. The parties do not undertake any obligation to update forward-looking statements contained in this press release.

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