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MabVax Therapeutics Reports Positive Safety Results from Initial Cohort of MVT-1075 Radioimmunotherapy Phase 1 Trial for the Treatment of Pancreatic, Colon and Lung Cancers

- Safety results in first cohort enable patient enrollment in second cohort at increased dose -**
- Tumor target specificity and accumulation of radiolabeled antibody demonstrated in first cohort of treated patients -**

SAN DIEGO, Feb. 28, 2018 /PRNewswire/ -- [MabVax Therapeutics Holdings, Inc.](#) (Nasdaq: MBVX), a clinical-stage biotechnology company focused on the development of antibody-based products to address unmet medical needs in the treatment of cancer, announced today positive interim results from the initial cohort of the Phase 1 clinical trial evaluating the Company's new human antibody-based radioimmunotherapy ("RIT") product MVT-1075 for the treatment of pancreatic, colon and lung cancer.



Results from the first three patients dosed in the initial cohort of this dose escalation Phase 1 safety trial demonstrated that MVT-1075 is reasonably well tolerated and accumulates on tumor as evidenced by dosimetry measurements performed after the first dose. At this initial dose, two subjects met the criteria for stable disease (SD) and one met

the criteria of progressive disease (PD) as measured using RECIST 1.1 criteria. Hematologic toxicities were manageable, and the Company is enrolling the first patient in the second cohort.

"We achieved our primary objectives in this early-stage clinical trial of our novel radioimmunotherapy product MVT-1075. We were able to establish safety at the first dose and generated our first clinical data with this product confirming targeting specificity and accumulation of the radiolabeled antibody on target lesions over time. The toxicities that emerged were expected and manageable. Having established safety at this first low dose level, we are now enrolling patients at the next planned dose and are optimistic that we will see impacts on tumor as we continue this study," commented [David Hansen, MabVax's President and Chief Executive Officer](#).

This Phase 1 first-in-human clinical trial is an open-label, multi-center study evaluating the safety and efficacy of MVT-1075 with CA19-9 positive malignancies in the U.S. The primary objective is to determine the maximum tolerated dose and safety profile in patients with recurring disease who have failed prior therapies. Secondary endpoints were to evaluate tumor response rate and duration of response by RECIST 1.1, and to determine dosimetry and pharmacokinetics. This dose-escalation study utilizes a traditional 3+3 design. The investigative sites include Honor Health in Scottsdale, Arizona and Memorial Sloan Kettering Cancer Center in New York City.

"We continue to believe that combining the clinically-demonstrated tumor targeting characteristics of our fully human HuMab-5B1 antibody and the commercially validated radionuclide, ¹⁷⁷Lutetium, we can deliver a lethal dose of radiation to the targeted cancer cells," added Mr. Hansen.

The Company previously reported preclinical results for MVT-1075 at the 2017 Annual Meeting of the American Association of Clinical Research (AACR), demonstrating marked suppression, and in some instances, regression of tumor growth in xenograft animal models of pancreatic cancer, potentially making this product an important new therapeutic agent in the treatment of pancreatic, colon and lung cancers. Supporting the MVT-1075 RIT clinical investigation are the Company's successful Phase 1a safety and target specificity data which were reported at the annual meetings of the American Society for Clinical Oncology (ASCO) and the Society for Nuclear Medicine and Molecular Imaging (SNMMI), including the clinical results for the Company's [MVT-5873](#) single agent therapeutic antibody and [MVT-2163](#), an immuno-PET imaging agent. The combined results from 50 patients in the Phase 1a MVT-5873 and MVT-2163 studies, established safety and provided significant insight into drug biodistribution and an optimal dosing strategy, which the Company has incorporated into the MVT-1075 program.

For additional information about the Phase 1 MVT-1075 clinical trial, please visit clinicaltrials.gov, and reference Identifier NCT03118349.

About MVT-1075

MVT-1075 is a radioimmunotherapy product that combines established efficacy of radiation therapy with tumor specific targeting. It has the potential to deliver a more potent HuMab-5B1 based product. MVT-1075 uses small doses of the Company's MVT-5873

antibody, coupled to a radioisotope to target pancreatic cancer cells and kill them.

About MabVax:

MabVax Therapeutics Holdings, Inc. is a clinical-stage biotechnology company with a fully human antibody discovery platform focused on the rapid translation into clinical development of products to address unmet medical needs in the treatment of cancer. Our antibody MVT-5873, is a fully human IgG1 monoclonal antibody (mAb) that targets sialyl Lewis A (sLea), an epitope on CA19-9, and is currently in Phase 1 clinical trials as a therapeutic agent for patients with pancreatic cancer and other CA19-9 positive tumors. CA19-9 is expressed in over 90% of pancreatic cancers and in other diseases including small cell lung and GI cancers. CA19-9 plays an important role in tumor adhesion and metastasis, and is a marker of an aggressive cancer phenotype. CA19-9 serum levels are considered a valuable adjunct in the diagnosis, prognosis and treatment monitoring of pancreatic cancer. With our collaborators including Memorial Sloan Kettering Cancer Center, Sarah Cannon Research Institute, Honor Health and Imaging Endpoints, we have treated 50 patients with either our therapeutic antibody designated as MVT-5873 or our PET imaging diagnostic product designated as MVT-2163 in Phase 1 clinical studies, and demonstrated early safety and specificity for the target. Patient dosing has commenced for our lead development program in Phase 1 clinical study of the Company's radioimmunotherapy product MVT-1075. For additional information, please visit the Company's website, www.mabvax.com.

Forward Looking Statements:

This press release on announcing results from the enrollment and dosing of patients in the initial cohort of the Phase 1 clinical trial evaluating the Company's new human antibody-based radioimmunotherapy ("RIT") product MVT-1075 for the treatment of pancreatic, colon and lung cancer contains "forward-looking statements" regarding matters that are not historical facts, including statements relating to the Company's clinical trials and product development pipeline. We have no assurance that all 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, 2016, 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. The parties do not undertake any obligation to update forward-looking statements contained in this press release.

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