September 20, 2016

MabVax Delivering 1-2 Punch with "Diagnose and Destroy" Cancer Pipeline

By Financial Press Staff

SAN DIEGO, Sept. 20, 2016 /PRNewswire/ - If the world is ever going to defeat cancer, innovation must remain robust to develop new cancer therapies. While new drugs are obviously important, the world also needs more precise cancer diagnostics to better detect cancer early and to more efficiently detect cancer cells before and after treatment.

While many companies focus on one cancer fundamental or the other, San Diego-based MabVax Therapeutics Holdings, Inc. (NASDAQ: MBVX) is using antibodies to address both diagnostics and therapeutics. Through exclusive agreements with Memorial Sloan Kettering Cancer Center (MSKCC), the company has blazed a new trail in oncology by establishing a portfolio of antibodies derived from blood samples of patients mounting an immune response subsequent to receiving cancer vaccine therapy at MSKCC.

In order to understand the close collaboration with MSKCC it is necessary to recognize MabVax co-founder Dr. Philip Livingston. Dr. Livingston, a Harvard medical school grad, served as Professor of Medicine in the Joan and Sanford Weill Medical College at Cornell University and Attending Physician and Member in MSKCC, where he treated melanoma patients and ran the Cancer Vaccinology Laboratory research lab for over 30 years until his retirement from MSKCC in 2011.

MabVax takes the MSKCC blood samples and sorts through them to find cells that are producing antibodies – proteins produced by B-cells and plasma cells that the immune system uses to recognize cancer cells – and then clones the antibody's DNA. Drilling down a little further, the company is searching for specific cells that produce specific antibodies that bind with specific antigens to combat tumors. As with other immunotherapies, once a particular antibody is identified for its tumor-targeting properties, it can be used as a standalone therapeutic agent or combined with a toxin to increase potency and destroy tumors.

"Over the years, we've become very efficient and optimized the discovery process," commented David Hansen, President and CEO at MabVax, in a phone conversation. "Not every antibody is useful at the outset, others needs a little engineering and others need essentially no engineering. The latter is exactly what we look for."

With MabVax's most advanced therapeutic, MVT-5873 (HuMab 5b1), the antibody didn't need any engineering. It already has strong tumor targeting capabilities by discriminately honing in on CA19-9, an antigen heavily expressed in many cancer types, and over 90% in pancreatic cancer.

According to the American Cancer Society, about 53,070 people (27,670 men and 25,400 women) will be diagnosed with pancreatic cancer in 2016 and approximately 41,780

people (21,450 men and 20,330 women) will die of pancreatic cancer. That means pancreatic cancer accounts for about 3 percent of all cancer cases in the U.S. and about 7 percent of cancer deaths, qualifying it as an area of great unmet medical need.

In February, MabVax initiated a Phase 1 multi-site trial (including MSKCC) of MVT-5873 in late-stage pancreatic cancer patients that have failed all other cancer therapies. The trial is structured so that the first group of patients is being administered escalating doses of MVT-5873 to evaluate the safety and tolerability and establish dosing for a Phase 2 study for the "naked therapy" (MVT-5873 alone). Later this year, patients will begin a combination therapy of MVT-5873 along with a standard of care chemotherapy, to evaluate the safety and tolerability of the cocktail treatment.

It's still early in the study, with nine patients with stage 3 and 4 cancer having exhausted all other treatment options now entered into the trial as of early September for the intended 28-day cycle under the study protocol. What is encouraging among these few patients is that several have remained on therapy at the investigator's initiative based on assessment of patient benefit. A Phase 1 trial is not powered for efficacy, but data does help delineate patient populations where the therapy may provide the most meaningful benefit going forward for MabVax. Preliminary results, which will provide a much closer look at the impact and pharmacokinetic profile of MVT-5873, are expected in the coming months.

This trial also has a twist that makes it different than a typical Phase 1 study. MabVax plans to add another group of patients to the trial aimed at treating earlier-stage pancreatic cancer patients once an acceptable safe dose is established, making it more of what could be considered a Phase 1/2 study.

While that trial is progressing, MabVax is also conducting a Phase 1 clinical trial of MVT-2163, a new combination of MVT-5873 and the radioisotope Zirconium 89 used in performing PET (positron emission tomography) scans. The goal of this study is to determine the best time and dose of the agents to deliver the best PET image of a pancreatic cancer tumor. Today, CT (computerized tomography) scans are commonly used in cancer, but they are limited in that while effective at highlighting major tumor sites, they disappoint in identifying smaller and metastasized sites.

This aligns with the "detect and destroy" methodology of MabVax in treating cancer; diagnose and identify with MVT-2163 and then attack the tumors with MVT-5873 (or a combination therapy). The trial is, similar to the therapeutic Phase 1 study, evaluating MVT-2163 in late-stage patients, those with disseminated disease. The trial is being conducted at MSKCC. If MVT-2163 can identify small and metastasized tumor sites, it will represent a significant advancement in cancer imaging in better predicting and monitoring disease progression and efficacy of therapy. Sadly, only about 16 percent of stage four patients with pancreatic neuroendocrine tumors that undergo surgery survive five years. Improving the diagnostic and treatment path has the potential to improve outcomes.

The company intends to publicize more details in an interim report in the fourth quarter 2016 and have both Phase 1 trials completed in mid-2017. This should arm MabVax with important data that larger biotechnology companies will be interested in. No matter how promising, big pharma tends to shy away from early-stage research until a larger data set

is compiled on safety, tolerability, targeting specificity of the antibody and, certainly, efficacy, but they don't like to miss out either. Overall, for a company sporting a market capitalization of only $30 million based on common stock outstanding, MabVax seems to be in a relatively unique position for a young company in the hot field of immuno-oncology with an attractive companion diagnostic.

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