Recombinant DNA Advisory Committee Submission
BB IND 7550
Protocol Number TG1031.03
Protocol Title: Phase I/II Trial of Antigen-Specific Immunotherapy in MUC1 Positive Patients with Adenocarcinoma of the Prostate Using Vaccinia Virus-MUC1-IL2

Non-Technical Abstract

This study involves the use of an experimental product, VV-MUC1-IL2, to determine if prostate cancer patients can be vaccinated against their tumor by stimulating the body's immune system to help it fight the cancer. Patients with metastatic prostate cancer who have a rising Prostate Specific Antigen (PSA) level and prostate cancer patients without metastatic disease who have a rising PSA level after being treated with surgery or radiation therapy may be eligible to enroll into this study. The experimental product is a modified Vaccinia virus (used in smallpox vaccinations) into which has been added genes for a protein found in cancer cells (MUC1) and interleuken 2 (IL2) which is part of the body's immune system. The VV-MUC1-IL2 is given as a shot in the muscle of the arm once every four (4) weeks for as long as it is tolerated. In the first part of the study, three doses will be tested. The first three patients will receive the lowest dose, 5×10^5 pfu. If, after one month, that dose is tolerated by the patients, the next three patients will be entered into the study and will receive the middle dose, 5×10^6 pfu. If this dose is tolerated, the next three patients enrolled will receive the highest dose of 5×10^7 pfu. After this part of the study is completed, approximately 25 additional patients will be enrolled at the highest tolerated dose. Patients will continue to receive the treatment every four weeks for as long as they tolerate the medication and their cancer does not progress. The purpose of the second part of the study is to determine if the VV-MUC1-IL2 can help control the growth of the cancer and to determine how safe it is.