

Recombinant DNA Advisory Committee Submission

BB IND 8147

Protocol Number TG4001.03

Protocol Title: Phase I/Trial of Immunotherapy with MVA-HPV-IL2 (TG4001) in Women with Advanced Cervical Carcinoma

Scientific Abstract

A phase I open label, dose-escalating, single center study comparing three dose levels (5×10^5 , 5×10^6 , and 5×10^7 p.f.u.) of Modified Virus Ankara-Human Papillomavirus-Interleukin-2 (TG4001) given by intramuscular injection every 3 weeks times 3. Patients will receive a single course of therapy followed by six months of observation. Women with no more than 1 previous chemotherapy regimen for metastatic or advanced, incurable cervical cancer, no prior immunotherapy, ECOG performance status of 0, 1, or 2, adequate immunologic, hematologic, hepatic and renal function, and a minimum life expectancy of at least 3 months are eligible for enrollment into this study.

The objective of this study is to determine safety and the maximum tolerated and biologically active dose, the cellular and humoral response to HPV E6 and E7, and any anti-tumor activity associated with MVA-HPV-IL2 vaccination. Dose escalation will continue to the MTD or 5×10^7 dose level, whichever occurs first. Patients will be assessed for safety, cellular and humoral responses to E6 and E7, and tumor evaluation.