

Recombinant DNA Advisory Committee Submission

BB IND 8559

Protocol Number TG4010.01

Protocol Title: Phase I Bridging Trial of TG4010 as Antigen-Specific Immunotherapy in Patients with MUC1 Positive Advanced Cancer

Scientific Abstract

A phase I open label, dose-escalating, single center study comparing 5×10^6 and 5×10^7 pfu dose levels of TG4010 (MVA-MUC1-IL2) given by intramuscular injection weekly times four (4) weeks. If there are no signs of disease progression, therapy can continue every other week for 4 cycles, then every 4 weeks. Patients may receive multiple courses of treatment as tolerated and will be followed until there is evidence of progressive disease. Inclusion criteria include: histologically confirmed, MUC-1 positive cancer refractory to standard anti-cancer therapy; ECOG PS of 0, 1, or 2; adequate hematologic, hepatic and renal function; ≥ 18 years old, not HIV+, no other serious concomitant systemic medical disorder. Cohorts of 3 patients will be successively enrolled into each dose level provided there are no Grade III or IV product related toxicity at the lower dose level. An additional 4-patients may be enrolled into the 5×10^7 dose level to confirm safety. Assessment criteria include the overall safety (frequency of adverse events and abnormal laboratory events), measurement of MUC-1 reactivity, antibody response to MUC-1 and MVA, and viral biodistribution.