

Recombinant DNA Advisory Committee Submission

BB IND 8028

Protocol Number TG1041.01

Protocol Title: Phase I/Trial of Immunotherapy with Adenovirus-Interferon- γ (TG1041) in Patients with Malignant Melanoma

Scientific Abstract

A phase I open label, dose-escalating, single center study comparing four dose levels (1×10^7 , 1×10^8 , 1×10^9 , and 1×10^{10} i.u.) of Adenovirus-Interferon- γ (TG1041) given by intratumoral injection weekly for 3 weeks. Patients will receive a single course of therapy. The objective of this study is to determine safety and the maximum tolerated and biologically active dose. Dose escalation will continue to the MTD or 1×10^{10} dose level, whichever occurs first. Tumor status will be documented by measurement of palpable tumors and radiographic documentation of non-palpable sites of disease as clinically indicated. Additional cycles may be given if there is evidence of tumor regression in the absence of tumor progression at other sites and the absence of any new sites of disease.