

1. Scientific Abstract:

Antigen presentation in the absence of costimulation results in anergy. This phase I study will evaluate the safety and the immunologic efficacy of a fowl pox vaccine containing the tumor associated antigen, carcinoembryonic antigen (CEA), and 3 costimulatory molecules, B7.1, ICAM-1 and LFA-3, alone or in conjunction with the adjuvant GM-CSF. Prior studies using another avipox vaccine, ALVAC CEA B7.1, demonstrated safety and immunologic efficacy in patients with CEA-expressing adenocarcinomas. Clinical evidence of activity has been suggested by declines in serum CEA and cases of mixed tumor responses. Preclinical studies have suggested enhanced responses to vaccines with GM-CSF, with conflicting clinical data on its efficacy. The current study will further assess the role of costimulation and GM-CSF given as a recombinant protein or as a fowlpox construct encoding the human GM-CSF gene.