

POSTER PRESENTATION

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Novel adenoviral serotype 5 based immunotherapeutic induces T-cell responses despite anti-adenoviral neutralizing antibodies in colorectal cancer patients

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Naturally occurring or induced Ad-specific neutralizing antibodies impeded the activity of recombinant Ad5-based vectors with E1 deletions. An improved Ad vector with deletions of the E1 and the E2b regions (Ad5 [E1-, E2b-]), the latter encoding the DNA polymerase and the preterminal protein, with significantly diminished late phase viral protein expression, were hypothesized to avoid immunological clearance and induce more potent immune responses against the encoded tumor antigen transgene in Ad-immune hosts. In the present phase I/II study, cohorts of patients with advanced metastatic colorectal cancer (mCRC) were immunized with escalating doses of Ad5 [E1-, E2b-]-CEA(6D). The carcinoembryonic antigen (CEA) transgene employed contains a modification (CAP1-6D) designed to enhance CTL stimulation. CEAspecific CMI responses were observed despite the presence of pre-existing Ad5 immunity in a majority (61.3%) of patients. Long-term follow-up in some of the patients reveled a waning of the induced CEA directed immune responses at around 6 months. Importantly, there was minimal toxicity, and overall patient survival (48% at 12 months) was similar regardless of pre-existing Ad5 neutralizing antibody titers. Our patient demographics, albeit limited in size, we similar with previously published studies of patients with chemotherapy-refractory mCRC. Of particular interest is the observation that treated mCRC patients in our study exhibited favorable survival probability. The results demonstrate that, in cancer

patients, the novel Ad5 [E1-, E2b-] gene delivery platform generates significant CMI responses to the tumor antigen CEA in the setting of both naturally acquired and immunization-induced Ad5-specific immunity.

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