ETBX-011: A replication-defective adenovirus expressing human carcinoembryonic antigen (CEA) containing an AdTag mutator at sites +1000 and +1250 (CEA(Δ2)). The adenovirus vector comprising this product has been modified by removal of the E1, E2b and E3 genes and insertion of a CEA gene. The resulting replication-defective vector can only be propagated in a newly developed proprietary human 205 cell line (EC2) that can supply the E1, E2b and E3 gene functions in trans.

Results: ETBX-011 was found to be well-tolerated at all doses and there were no drop outs due to treatment. Specific anti-CEA immune responses were observed in the majority of patients and median overall survival was 11 months. We now report on long-term follow-up of the patients. Forty-four percent (44%) of patients still survived at 12 months follow-up and 33% at 18 months following treatments. One patient (1/17, 6%) developed a treatment-related grade 3 hematologic adverse event. Fifty-six percent (56%) of patients showed a decrease in the Th1:Th2 ratio on follow-up and still survived at 2 years post-treatment. Conclusions: These results demonstrate that mCRC patients treated with ETBX-011 immunotherapeutic is safe and can be easily administered to patients. ETBX-011 treatment generated significant CMI induction to the tolerated tumor associated antigen CEA and may experience increased overall survival. A single agent randomized, multicenter Phase 2b trial is being initiated to further evaluate the clinical effects.

2. Overall Survival

Overall survival of patients treated with ETBX-011 was monitored throughout the study. Patients treated at least two times with ETBX-011 were followed for survival (n = 31). There was no correlation between the AdTag NAb levels and survival (n = 31) indicating that pre-existing AdTag immunity did not affect survival following immunization. The median overall survival for all patients in the trial was 11 months. At 23 months post initial treatment over 50% of mCRC patients that received ETBX-011 remained alive.