**ABSTRACT**

**BACKGROUND: Preclinical Data**

** Yeast as a Recombinant Vector  
- Easily engineered to express transgenes (such as the CEA antigen)  
- Cultured rapidly in large quantities  
- Can be administered multiple times  
- Recruits and matures dendritic cells

** Yeast CEA Phase I Trial  
- Enrolled 25 patients with advanced carcinoma (22 colorectal patients, 1 each with medullary thyroid cancer, pancreatic cancer and lung cancer)  
- Patients were heavily pre-treated (median 4 previous chemotherapy regimens)  
- There was no DLT (max dose of 40 Yeast Units (YU))  

** Yeast CEA Vaccine is Well Tolerated  
- Vaccines may have a different impact than chemotherapy  
- Medullary Thyroid Cancer may be ideal for vaccine therapy

** Yeast CEA Improves Survival in a Pulmonary Metastasis Model  
- In vitro responses to human dendritic cells from  
- Clinical and immunologic outcomes  
- Although these were heavily pre-treated patients with advanced disease, 5 patients had  
  stable disease beyond 3 months and all 5 had stabilization of their serum CEA

** Yeast CEA Vaccine Results in Phenotypic Maturation of Immature Myeloid Dendritic Cells (DC)  
- DCs treated with CEA + yeast  
- DCs treated with superantigen

** Yeast CEA Vaccine for 1 year (n=17)  
- Patients are re-staged at 3 month intervals while on vaccine

** Yeast CEA Vaccine for 1 year  
- Surveillance for 6 months (n=17)  

** Yeast CEA Vaccine for 1 year  
- Patients randomized to  
  - Vaccine for 1 year  
  - 6 months of surveillance followed by vaccine for 1 year

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