Adaptive transfer of T cell receptor (TCR) gene-engineered T cells can induce durable anti-cancer responses. Post-infection cytokine release syndrome (CRS) has been associated with clinical side effects with CAR-T cells. NY-ESO-1 is a novel gene therapy approach using genetically modified T cells to target a tumor-specific antigen.

**BACKGROUND**

Adaptive transfer of T cell receptor (TCR) gene-engineered T cells can induce durable anti-cancer responses. Post-infection cytokine release syndrome (CRS) has been associated with clinical side effects with CAR-T cells. NY-ESO-1 is a novel gene therapy approach using genetically modified T cells to target a tumor-specific antigen.

**Trial Design and Key Inclusion**

- **Cohort A**: Single treatment of TBI-1301
- **Cohort B**: Retreatment for patients who have persisting disease following NY-ESO-1 TBI-1301
- **Cohort C**: Double treatment of TBI-1301 on Days 0 and 14

**Clinical Results**

- **CLINICAL RESULTS**
  - **Study Days**
  - **Cohort A:** Single treatment of TBI-1301
  - **Cohort B:** Retreatment for patients who have persisting disease following NY-ESO-1 TBI-1301
  - **Cohort C:** Double treatment of TBI-1301 on Days 0 and 14

**Biomarker Correlates**

- **Detection of NY-ESO1-specific CD4 and CD8 T cells in peripheral blood**
  - **Percentage of NY-ESO1-specific CD4 and CD8 T cells**
  - **Clinical significance**

**Conclusion**

- **Repeated infusion of TBI-1301 is well tolerated and induces clinical responses in HA-0.023+ patients with NY-ESO-1+ tumors**
- **Addition of fludarabine may contribute to longer persistence of NY-ESO-1 TCR-T cells**
- **Further characterization of long persisting TBI-1301 cells is ongoing**

**Abstract Text**


**Tumor Immunotherapy Program, Princess Margaret Cancer Centre, University of Toronto, **Takauro Bio Inc, Japan

NCT02869217

marcus.butler@uhn.ca