A Phase I/II Trial Investigating Safety and Efficacy of Autologous T Cell Antigen-Coupler (TAC) T Cells Targeting HER2 in Relapsed or Refractory Solid Tumors (TACTIC-2).

**BACKGROUND:** Despite recent therapeutic advances for patients with breast, colorectal and gastroesophageal cancers with HER2 overexpression, there is still a significant unmet medical need for better treatment options for HER2-positive solid tumors, especially those with low or intermediate HER2 expression (1+ and 2+) by immunohistochemistry (IHC). The T Cell Antigen-Coupler (TAC) technology is a novel way to genetically modify T cells and to redirect these T cells to target cancer antigens and to activate T cells naturally by co-opting the natural T cell Receptor (TCR).

**TAC SCIENCE**

**Key features of TAC Technology:**
- **TAC** functions independently of MHC
- **TAC** requires endogenous TCR for T cell activation
- **TAC** incorporates the CD4 co-receptor and recruits the TCR complex, mimicking natural T cell activation

**PRECLINICAL DATA**

**OBJECTIVES ENDPOINTS**

**PRIMARY:** To evaluate the safety of TAC01-HER2 in subjects with HER2+ solid tumors
- Incidence of Dose Limiting Toxicities (DLTs); Adverse events (AEs) and laboratory abnormalities

**SECONDARY:** To determine the M1 and RP2D for TAC01-HER2
- Incidence of DLTs

**SECONDARY:** To characterize the pharmacokinetic (PK) profile of TAC01-HER2
- Cmax, Tmx, and AUC of TAC01-HER2 cells
- Duration of persistence of TAC01-HER2 cells

**SECONDARY:** To evaluate the efficacy of TAC01-HER2
- Response Evaluation Criteria in Solid Tumors (RECIST) Criteria Version 1.1 Overall Response Rate (ORR) Duration of Response (DOR) Overall Survival (OS)

**EXPLORATORY:** Biomarker Studies to characterize T-cells and clinical outcomes (safety and efficacy)

**TACTIC-2 Study Design**

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