# MT2024-33 A Phase 1/2a Multicenter Ascending Dose Study to Evaluate the Safety of HA-1 Minor Histocompatibility Antigen-Reactive TCR-Modified T Cells (BSB-1001) in Patients Undergoing HLA-Matched Allogenic Hematopoietic Stem Cell Transplant for AML, ALL or MDS

**Status:** Recruiting

## Eligibility Criteria

**Sex:** Male or Female
**Age Group:** 18 years and over
This study is NOT accepting healthy volunteers

**Inclusion Criteria:**

- ages 18

•70 years inclusive, having a alloHCT. - any of the following high-risk hematologic malignancies: • AML which has been treated with at least two lines of therapy, and refractory or relapsed • ALL • MDS after at least one line of therapy, which includes hypomethylating agent(s) and venetoclax and must be high or very high risk • AML patients who have been treated with at least two lines of therapy, and refractory or relapsed - suitable for one of the approved conditioning regimens as defined in the protocol - must have an identified donor that is HA 1-negative with 10/10 matched related donor or 12/12 matched unrelated donor - see link to clinicaltrials.gov for complete inclusion and exclusion criteria

**Exclusion Criteria:**

- weight \> 100 kg. (220 lbs) - prior history of allogeneic or autologous stem cell transplantation - previous genetically engineered chimeric antigen receptor T Cell therapy (CAR-T), approved or investigational, within 2 years of screening, with the exception of patients with ALL previously treated with an autologous CAR-T product. - recent treatment with other investigational agents - history of treatment with checkpoint inhibitor therapy within 3 months of transplantation - women who are pregnant or breast feeding - uncontrolled bacterial, viral, or fungal infections - CNS involvement that hasn't responded to intrathecal chemotherapy and/or standard cranial- spinal radiation. - unable to work; able to live at home and care for most personal needs; requires occasional assistance, but is able to care for most personal needs or better performance

## Conditions & Interventions

**Interventions:**
Drug: SOC + BSB-1001 Dose Escalation Cohort, Drug: SOC+BSB-1001 Expansion Dose
**Conditions:**
Cancer
**Keywords:**
ALL, AML, MDS, stem cell transplant, Clinics and Surgery Center (CSC), Adult Recurrent

## More Information

**Description:** This study is designed to determine whether BSB-1001 - a product made of genetically modified cells - is safe and possibly effective when given to patients with Acute Myelogenous Leukemia (AML), Acute Lymphocytic Leukemia (ALL), or Myelodysplastic Syndrome (MDS) who are also receiving a stem cell transplant with a matched donor.
**Study Contact:** Mark Juckett - juck0001@umn.edu
**Principal Investigator:** Mark Juckett
**Phase:** PHASE1
**IRB Number:** STUDY00023637