Protocol Title: Phase III Randomized Trial of Blinatumomab for Newly Diagnosed BCR-ABL-Negative B Lineage Acute Lymphoblastic Leukemia in Adults

Target Population: Acute Lymphoblastic Leukemia (ALL)
- B Cell Acute Lymphoblastic Leukemia, Philadelphia Chromosome Negative
- Adult B Acute Lymphoblastic Leukemia
- Untreated Adult Acute Lymphoblastic Leukemia

Summary: To compare the Overall Survival (OS) of Blinatumomab in conjunction with chemotherapy to chemotherapy alone in patients with BCR-ABL-Negative B Cell precursor Acute Lymphoblastic Leukemia (ALL) who are Minimal Residual Disease (MRD) Positive after induction and intensification chemotherapy, based on Multiparameter Flow Cytometric (MFC) Assessment of Residual Blasts.

Key Inclusion Criteria:
- PRE-REGISTRATION:
  - Diagnostic bone marrow and peripheral blood specimens must be submitted for immunophenotyping and selected molecular testing, and the establishment of BCR/ABL status.
- INDUCTION ELIGIBILITY CRITERIA-STEP 1:
  - New diagnosis of B Lineage ALL.
  - Mature B ALL (Burkitt’s-like Leukemia) is excluded from enrollment in this trial.
  - Negativity for the Philadelphia Chromosome.
- POST-INDUCTION THERAPY ELIGIBILITY CRITERIA (PRIOR TO INTENSIFICATION-STEP 2):
  - Patients must have achieved a CR or Cri.
  - Patients who have achieved a CR or CRi must have maintained peripheral blood evidence of a CR or CRi.
  - Patient must be CNS (cerebrospinal fluid [CSF]) negative for leukemia.
- RANDOMIZATION TO BLINATUMOMAB OR NO BLINATUMOMAB-STEP 3:
  - Patients must have maintained peripheral blood evidence of a remission and must have a CR or CRi, confirmed on restaging bone marrow (BM) aspirate and biopsy and cytogenetic analysis.
  - Bone marrow aspirates must be submitted for centralized minimal residual disease.
- CRITERIA FOR ALLOGENEIC TRANSPLANTATION:
  - A suitable donor must be identified.
    - Note: There are no restrictions on donor type and can include a matched sibling, a matched or mismatched unrelated donor, a family haplotype matched donor or a cord blood donor (single or double).
  - Patients should meet the eligibility criteria for Randomization to Blinatumomab or no Blinatumomab-Step 3.
- CRITERIA FOR MAINTENANCE THERAPY-STEP 4:
  - Patients must have maintained peripheral blood evidence of a remission and must have a CR or CRi, confirmed on restaging BM aspirate and biopsy and cytogenetic analysis.

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For additional information: https://clinicaltrials.gov/ct2/show/study/NCT02003222