

Study of Efficacy and Safety of Tisagenlecleucel in HR B-ALL EOC MRD Positive Patients

Status: Recruiting

Eligibility Criteria

Age: 1 year to 25 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. CD19 expressing B-cell Acute Lymphoblastic Leukemia 2. De novo NCI HR B-ALL who received first-line treatment and are MRD \geq 0.01% at EOC. EOC bone marrow MRD will be collected prior to screening and will be assessed by multi-parameter flow cytometry using central laboratory analysis. 3. Age 1 to 25 years at the time of screening 4. Lansky (age < 16 years) or Karnofsky (age \geq 16 years) performance status \geq 60% 5. Adequate organ function during the screening period: A. Renal function based on age/gender B. ALT \leq 5 times ULN for age C. AST \leq 5 times ULN for age D. Total bilirubin < 2 mg/dL (for Gilbert's Syndrome subjects total bilirubin < 4 mg/dL) E. Adequate pulmonary function defined as:

- no or mild dyspnea (\leq Grade 1)

- oxygen saturation of > 90% on room air F. Adequate cardiac function defined as LVSF \geq 28% confirmed by echocardiogram or LVEF \geq 45% confirmed by echocardiogram or MUGA within 6 weeks of screening 6. Prior induction and consolidation chemotherapy allowed: 1st line subjects: \leq 3 blocks of standard chemotherapy for first-line B-ALL, defined as 4-drug induction, Berlin-Frankfurt-Münster (BFM) consolidation or Phase 1b, and interim maintenance with high-dose methotrexate.

Exclusion Criteria:

1. M3 marrow at the completion of 1st line induction therapy 2. M2 or M3 marrow or persistent extramedullary disease at the completion of first-line consolidation therapy or evidence of disease progression in the peripheral blood or new extramedullary disease prior to enrollment. Patients with previous CNS disease are eligible if there is no active CNS involvement of leukemia at the time of screening. 3. Philadelphia chromosome positive ALL 4. Hypodiploid: less than 44 chromosomes and/or DNA index < 0.81, or other clear evidence of a hypodiploid clone 5. Prior tyrosine kinase inhibitor therapy 6. Subjects with concomitant genetic syndromes associated with bone marrow failure states: such as subjects with Fanconi anemia, Kostmann syndrome, Shwachman syndrome or any other known bone marrow failure syndrome. Subjects with Down syndrome will not be excluded. 7. Subjects with Burkitt's lymphoma/leukemia (i.e. subjects with mature B-ALL, leukemia with B-cell [slg positive and kappa or lambda restricted positivity] ALL, with FAB L3 morphology and /or a MYC translocation) 8. Has had treatment with any prior anti-CD19 therapy 9. Treatment with any prior gene or engineered T cell therapy Other protocol-defined inclusion/exclusion may apply.

Conditions & Interventions

Interventions:

Biological: CTL019

Conditions:

B-cell Acute Lymphoblastic Leukemia

Keywords:

CTL019, Kymriah, B-Cell Acute Lymphoblastic Leukemia, ALL, tisagenlecleucel, HR B-ALL EOC MRD, Minimal Residual Disease (MRD), Positive at the End of Consolidation (EOC)

More Information

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Phase: Phase 2

IRB

Number: HM20022023

System ID: NCT03876769

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