# Acute Lymphoblastic Leukemia (ALL) CAR-T Eligibility Criteria

## Treatment History & Prognosis

- □ Patient has CD19+ B-cell acute lymphoblastic leukemia (ALL) and is one of the following:
  - a. refractory
  - b. has relapsed after allogeneic stem cell transplant *(CAR-T infusion must be at least 4 months from time of SCT)*
  - c. has experienced second or later relapse
  - d. Ineligible for allogeneic SCT because of:
    - Comorbid disease
    - Other contraindications to allogeneic SCT conditioning regimen
    - Lack of suitable donor
    - Prior SCT
    - Declines allogeneic SCT as a therapeutic option after documented discussion about the role of SCT with a BMT physician not part of the study team
- □ Patient is 18 to 25 years inclusive
- □ Patient is clinically stable and expected to remain so through to the planned CAR T-cell infusion date. Patient is expected to tolerate the therapy based on organ function criteria summarized below.
- □ Karnofsky Performance Score (KPS) ≥ 50%
- □ Patients with Ph+ ALL are eligible if they are intolerant to or have failed two lines of TKI therapy, or if TKI therapy is contraindicated

## Organ Function

Patients must have adequate organ function and sufficient T cells to allow a successful apheresis. The ranges below are a guide for your patient to qualify for CAR-T*. Patients not fulfilling specific criteria can still be considered on a case-by-case basis. Please discuss with transplant team.

### Renal function:
- A serum creatinine ≤ 150.31 μmol/L
- ALT ≤ 5 times the ULN for age

### Liver function:
- Bilirubin < 2.0 mg/dl

### Pulmonary function:
- Pulse oxygenation > 91% on room air

### Cardiac function:
- LVSF ≥ 28% confirmed by echocardiogram
- Left ventricle ejection fraction (LVEF) ≥ 45% confirmed by echocardiogram or Multigated Radionuclide Angiography (MUGA)

### Lymphocyte count:
- Absolute lymphocyte count (ALC) > 0.1 x 10^9/L (100/mm^3) NOTE: If ALC is below 0.1 x 10^9/L, application can be considered; but for apheresis to proceed, ALC must be at least 0.1 x 10^9/L

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*CAR-T*
<table>
<thead>
<tr>
<th>Exclusion Criteria</th>
<th>Possible exclusion criteria:</th>
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<tbody>
<tr>
<td></td>
<td>Active CNS involvement, defined as CNS-3 per NCCN guidelines. Note: Patients with history of CNS disease that has been effectively treated will be eligible.</td>
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<tr>
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<td>Active uncontrolled Hepatitis B, Hepatitis C or HIV infection</td>
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<td>Active uncontrolled GVHD with need for ongoing immunosuppression</td>
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<td>Prior treatment with genetically engineered T cell product</td>
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