Haploidentical Donor Cytokine-Induced Memory-Like Natural Killer Cells (CIML-NK) for Relapsed & Refractory Neuroblastoma

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 1 year to 39 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Age 1-39 years at the time of study enrollment
- With diagnosis of neuroblastoma with histologic verification
- Classified as high-risk neuroblastoma as defined by Children's Oncology Group (COG) risk classification, including patients initially classified as low or intermediate risk at diagnosis with subsequent reclassification as high-risk disease
- With relapsed or refractory disease, including at least one of the following:

1. Recurrent disease at any time after completion of frontline therapy
2. Progressive disease at any time following standard induction therapy
3. Primary resistant or refractory disease defined by failure to achieve a complete response by International Neuroblastoma Response Criteria (INRC) after at least four cycles of standard, multidrug induction chemotherapy on or according to a high-risk neuroblastoma protocol
    - Patients must have evaluable disease documented within four weeks of study enrollment. Evaluable disease must include at least one of the following:
4. Measurable tumor (>10 mm in at least one dimension) on MRI or CT scan that is either MIBG, FDG or 68Ga-DOTATATE avid
5. One or more MIBG, FDG, or 68Ga-DOTATATE avid bone lesion
6. Microscopic marrow metastasis based on routine morphology and/or immunohistochemistry in at least one sample from bilateral aspirates and biopsies at the time of study enrollment.
    - With performance level of >50% on Lansky (<16 years) or Karnofsky (>16 years) scales. Patients who are wheelchair bound due to paralysis will be considered ambulatory when assessing their performance score.
    - Adequate baseline cardiac and pulmonary function including a left ventricular ejection fraction (LVEF) >50% by echocardiogram and pulse oximetry >92% on room air documented within four weeks of study enrollment.
    - Adequate baseline hematologic function: peripheral absolute neutrophil count (ANC) ≥500/µL, with no receipt of long-acting myeloid growth factors within 14 days or short-acting myeloid growth factors within 7 days of study entry, and a platelet count ≥50,000/µL, with patients required to be transfusion independent for at least 7 days, unless cytopenias are related to marrow metastasis as defined above.
    - With available haploidentical related donors.

Exclusion Criteria:

- Infectious disease: Active, uncontrolled infection or received a live vaccine within 30 days prior to study enrollment.
- Cardiac function: LVEF <50% by echocardiogram, serious uncontrolled cardiac arrhythmias, or history of myocarditis or congestive heart failure (New York Heart Association Functional Classification III or IV)
- Pulmonary function: Active interstitial lung disease (ILD)/pneumonitis or history of ILD/pneumonitis requiring systemic corticosteroid treatment.
- Renal function: Glomerular Function Rate (GFR) <50 mL/min/1.73 m2 as measured by cystatin C or NM GFR
- Hepatic function: Total bilirubin >5 mg/dL, AST and ALT >10 times the upper limit of normal
- Concomitant medications: receiving >0.5 mg/kg prednisone equivalent daily
- Receipt of any concomitant investigational treatments within 30 days at the time of the infusion of the IP. These investigational treatments include drugs, biologics, or devices that are still under investigation in clinical trials or research settings. The use of such agents may confound study results or pose additional safety risks
- Known allergy or hypersensitivity reaction to IL-2 injections
- Pregnant or breastfeeding women

Conditions & Interventions

Interventions:
BIOLOGICAL: CIML-NK Cells
Conditions:
Neuroblastoma

More Information

Description:
The goal of this study is to demonstrate that cytokine-induced memory-like natural killer cells (CIML-NK cells) can be generated from donor cells and infused safely into patients with relapsed or refractory neuroblastoma during dinutuximab-based therapy.

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Phase: PHASE2
IRB Number:
System ID: NCT07635056
