

SPEARHEAD-3 Pediatric Study

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 2 years to 21 years old

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

- Subject has histologically confirmed diagnosis of any one of the following cancers: (A) Synovial Sarcoma (SS), (B) MPNST, (C) Neuroblastoma, or (D) Osteosarcoma (OS).
- Age:

(A) Synovial Sarcoma: 2 to 17 years (B) MPNST, Neuroblastoma and Osteosarcoma: 2 to 21 years

- Body weight $\geq$ 10 kg
- Must have previously received a systemic chemotherapy
- Measurable disease prior to lymphodepletion according to RECIST v1.1 (or INCR, 2017 Neuroblastoma only).
- HLA-A*02 positive
- Tumor shows MAGE-A4 expression confirmed by central laboratory.
- Performance Status:

(A) Subjects $\geq$ 16: Eastern Cooperative Oncology Group (ECOG) 0 or 1 (B) Subjects 2 to 16: Lansky score $\geq$ 80

- Subject has anticipated life expectancy of greater than 3 months in the opinion of the investigator.

Exclusion Criteria:

- Positive for HLA-A*02:05 in either allele; or any A*02 having same protein sequence as HLA-A*02:05
- History of allergic reactions attributed to compounds of similar chemical or biologic composition to fludarabine, cyclophosphamide.
- History of autoimmune or immune mediated disease
- Known central nervous system (CNS) metastases.
- Other prior malignancy that is not considered by the Investigator to be in complete remission
- Clinically significant cardiovascular disease
- Active infection with human immunodeficiency virus, hepatitis B virus, hepatitis C virus, or human T cell leukemia virus
- Pregnant or breastfeeding
- Experiencing ongoing rapid disease progression that in the opinion of the Investigator significantly increases the subjects risk associated with treatment.

Conditions & Interventions

Interventions:

GENETIC: Afamitresgene autoleucel

Conditions:

Synovial Sarcoma, Malignant Peripheral Nerve Sheath Tumor (MPNST), Neuroblastoma (NBL), Osteosarcoma

More Information

Description:

This is a pediatric basket study to investigate the safety and efficacy of afamitresgene autoleucel in HLA-A*02 eligible and MAGE-A4 positive subjects aged 2-17 years of age with advanced cancers.

Contact(s): - cancer@cchmc.org

Principal Investigator:

Principal Investigator ID:

Phase: PHASE1

IRB Number:

System ID: NCT05642455

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