

Efficacy and Safety Study of Narsoplimab in Pediatric Patients With High-Risk Hematopoietic Stem Cell Transplant TMA

NCT05855083

Status	RECRUITING
Phase	Phase 2
Sponsor	Omeros Corporation
Enrollment	18 participants

Key Eligibility Criteria

Inclusion (20)

- Age at least 28 days and less than 18 years prior to informed consent (Visit 0).
- Have informed consent from at least one parent or legal guardian as required by local law and regulation. Patient informed consent will be required if the patient has reached the local legal age of majority.
- Assent from patients as required by local law and regulation.
- Have received an allogeneic hematopoietic stem cell transplant for the treatment of benign or malignant disease.
- Have a diagnosis of HSCT-TMA defined as meeting both of the following criteria:
... and 15 more (see full listing online)

Exclusion (14)

- All treatments for HSCT-TMA are allowed except eculizumab, ravulizumab, and defibrotide within 3 months prior to informed consent, unless failure of therapy can be documented.
- a. Patients may not be on eculizumab, ravulizumab, or defibrotide for any indication at screening.
- Have Shiga toxin-producing Escherichia coli haemolytic uraemic syndrome (STEC-HUS). Test results obtained within 28 days prior to informed consent may be used.
- Have ADAMTS13 activity \leq 10%. Test results obtained within 28 days prior to informed consent may be used.
- Have a severe, uncontrolled systemic bacterial or fungal infection requiring antimicrobial therapy, or a severe uncontrolled viral infection (as determined by the investigator); prophylactic antimicrobial therapy administered as standard of care is allowed.
... and 9 more (see full listing online)

Locations (16 total)

Omeros Investigational Site, San Diego, California, United States
Omeros Investigational Site, Gainesville, Florida, United States
Omeros Investigational Site, Boston, Massachusetts, United States
... and 13 more locations