Donor Virus-Specific CMV or AdV CTL to Treat CMV or AdV Reactivation or Disease After Solid Organ or HCT

NCT03665675

Status	RECRUITING
Phase	Early Phase 1
Sponsor	Sumithira Vasu
Enrollment	20 participants

Key Eligibility Criteria

Inclusion (21)

- Patients must have solid organ transplant or have received allogeneic hematopoietic stem cell transplant.
- • Cohort A (CMV): Must have documented CMV disease or reactivation, as by:
- Viremia as detected by quantitative polymerase chain reaction (PCR) (\> 500 IU/ml) in the peripheral blood requiring treatment OR
- High risk for antiviral failure due to history of recurrent CMV reactivations or evidence of antiviral drug resistance, OR
- Unable to tolerate antiviral drugs due to renal toxicity, bone marrow suppression, transfusion dependent anemia and thrombocytopenia or neutropenia requiring growth factor support or other related organ injury

... and 16 more (see full listing online)

Exclusion (10)

- Receipt of anti-thymocyte globulin (ATG), alemtuzumab, or other T-cell depleting agents within 21 days of screening for enrollment.
- Receipt of \> 0.5mg/kg/day of prednisone or steroid equivalent at the time of enrollment. Stable GVHD is permitted as long as patients are on stable dose steroids of less than or equal to 0.5 mg/kg/day of prednisone or steroid equivalent.
- Evidence of uncontrolled infection as follows:
- Bacterial infections - patients must be receiving definitive therapy and have no signs of progressing infection for 72 hours prior to enrollment.
- Fungal infections - patients must be receiving definitive systemic anti-fungal therapy and have no signs of progressing infection for 1 week prior to enrollment.

... and 5 more (see full listing online)

Locations (2 total)

Nationwide Children's Hospital, Columbus, Ohio, United States
Ohio State University Comprehensive Cancer Center, Columbus, Ohio, United States