Study of Posoleucel (ALVR105, Formerly Viralym-M) for Multi-Virus Prevention in Patients Post-Allogeneic Hematopoietic Cell Transplant

Status: Recruiting

Eligibility Criteria

Age: 1 year and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Key

Inclusion Criteria:

- ≥1 year of age at the day of screening visit.
- No known or suspected clinically significant disease from AdV, BKV, CMV, EBV, HHV-6, and/or JCV
- Within 15 and 42 days of receiving a first allogeneic HCT and have demonstrated clinical engraftment
- · Meet one or more of the following criteria at the time of randomization:
- Related (sibling) donor with at least one mismatch at one of these HLA-gene loci: HLA-A, -B or -DR
- · Haploidentical donor
- · Matched or Mismatched unrelated donor
- · Use of umbilical cord blood as stem cell source
- Ex vivo graft manipulation resulting in T cell depletion
- Received anti-thymocyte globulin or alemtuzumab (Campath-1H) Key

Exclusion Criteria:

- · History of AdV, BKV, CMV, EBV, HHV-6, and/or JCV end-organ disease within 6 months prior to randomization
- Evidence of active Grade >2 acute GVHD
- Presence of non-minor uncontrolled or progressive bacterial, viral or fungal infections
- Known history or current (suspected) diagnosis of CRS requiring treatment associated with the administration of peptides, proteins, and/or antibodies
- · Ongoing therapy with high-dose systemic corticosteroids (ie, prednisone equivalent dose >0.5 mg/kg/day) within 24 hours prior to dosing
- Relapse of primary malignancy other than minimal residual disease Note: Other protocol defined Inclusion/Exclusion criteria may apply.

Conditions & Interventions

Interventions:

Biological: Posoleucel (ALVR105), Biological: Placebo

Conditions

Adenovirus Infection, BK Virus Infection, Cytomegalovirus Infections, Epstein-Barr Virus Infections, Human Herpes Virus-6 Infection, JC Virus Infection

Keywords:

Allogeneic Hematopoietic Cell Transplant, ALVR105, Posoleucel, Viralym-M

More Information

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Number:

System ID: NCT05305040

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