Study to Evaluate Viralym-M (ALVR105) for the Treatment of Virus-Associated Hemorrhagic Cystitis (HC)

Status: Recruiting

Eligibility Criteria

Age: 1 day and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Key Inclusion Criteria Participants must meet all of the following criteria in order to be eligible to participate in the study:

• Male or female ≥1 year of age.

• Had an allogeneic hematopoietic cell transplant (HCT) performed ≥21 days and ≤1 year prior to randomization.

• Myeloid engraftment confirmed, defined as an absolute neutrophil count ≥500/mm³ for 3 consecutive laboratory values obtained on different days, and platelet count >10,000/mm³ at the time of randomization.

• Diagnosed with HC based on the following criteria (all 3 criteria must be met): 1. Clinical signs and/or symptoms of cystitis. 2. Grade ≥3 hematuria, defined as macroscopic hematuria with visible clots. 3. Viruria with ≥1 target virus (ie, BKV, JCV, AdV, CMV, EBV, and/or HHV-6).

• At least 1 identified, suitably matched posoleucel (ALVR105) cell line for infusion is available. Key Exclusion Criteria Participants who meet any of the following criteria will be excluded from participation in the study:

• Ongoing therapy with high-dose systemic corticosteroids (ie, prednisone dose >0.5 mg/kg/day or equivalent).

• Therapy with antithymocyte globulin, alemtuzumab (Campath-1H), or other immunosuppressive T cell-targeted monoclonal antibodies ≤28 days before randomization.

• Evidence of active Grade >2 acute graft versus host disease (GVHD).

• Uncontrolled or progressive bacterial or fungal infections.

• Uncontrolled or progressive viral infections not targeted by posoleucel (ALVR105).

• Uncontrolled or progressive EBV-associated post-transplant lymphoproliferative disorder.

• Known or presumed pneumonia secondary to any organism that is not considered to be well-controlled by antimicrobial therapy.

• Pregnant or lactating or planning to become pregnant. Note: Other protocol defined Inclusion/Exclusion criteria may apply.

Conditions & Interventions

Interventions:
Biological: Posoleucel (ALVR105), Biological: Placebo
Conditions:
BK Virus Infection, Hemorrhagic Cystitis
Keywords:
Allogeneic Hematopoietic Cell Transplant, ALVR105, Posoleucel

More Information

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