Phase 3 Multicenter, Double-Blind, Placebo-Controlled Trial of Viralym-M;(ALVR105) for the Treatment of Patients With Virus-Associated Hemorrhagic Cystitis After Allogeneic Hematopoietic Cell Transplant

Status: Recruiting

Eligibility Criteria

Sex: All
Age: Not specified
This study is NOT accepting healthy 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 â‰¥1 year of age.

• Had an allogeneic hematopoietic cell transplant (HCT) performed â‰¥21 days and â‰¤1 year prior to randomization.

• Myeloid engraftment confirmed, defined as an absolute neutrophil count â‰¥500/mmÂ³ for 3 consecutive laboratory values obtained on different days, and platelet count >10,000/mmÂ³ 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 â‰¥3 hematuria, defined as macroscopic hematuria with visible clots. 3. Viruria with â‰¥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 â‰¤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, Clinics and Surgery Center (CSC)

More Information

Description: The study hypothesis is that the administration of Viralym-M to patients with virus-associated HC will demonstrate superiority for the time to resolution of HC (as measured by resolution of macroscopic hematuria) compared to patients treated with placebo. The primary hypothesis will be tested in patients with BKV viruria to demonstrate superiority over placebo in this population (BK Intent-to-Treat [ITT] Population). A supplementary analysis will be conducted in all patients with any viral-associated HC (BKV, JCV, AdV, EBV, CMV, and/or HHV-6) in order to evaluate efficacy in this broader population (ITT Population). Further detail is provided in the statistical section below and will be described in the Statistical Analysis Plan (SAP).
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