A Phase 3 Trial to Compare IV BCV Versus IV CDV for Treatment of Adenovirus Infection After Allo-HCT

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 2 month(s) and over
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

1. Male and female, post-allo HCT within last 180 days, aged 2 months and older at time of signing informed consent form.
2. Subject/Guardian willing and able to understand and provide written informed consent to participate in the study.
3. In the investigator's judgement, the subject's clinical condition justifies treatment with IV BCV or IV CDV for AdV infection.
4. Has adenoviremia, based on any of:

- AdV viremia DNA ≥10,000 IU/mL, OR
- Two consecutive and rising AdV viremia DNA results of ≥1,000 IU/mL at screening, OR
- AdV viremia DNA of ≥1,000 IU/mL, AND

1. Lymphocyte count <180/mm3, OR 2. Received T cell depletion, cord blood, or haploidentical transplant, OR 3. prior alemtuzumab, OR 4. anti-thymocyte globulin (ATG)

Exclusion Criteria:

1. Subject received an allo-HCT with a matched sibling donor
2. Subject received more than 5 mg/kg of CDV for any reason in the 21 days prior to first dose of study drug.
3. Subject is allergic or hypersensitive to IV BCV or IV CDV or any of their components.
4. Subject received anti-AdV-specific cell-based therapy within 3 weeks prior to W1D1 or an anti-AdV vaccine at any time.
5. Subject has participated in any other investigational study within 30 days (or within 5.5 half-lives of the investigational product, whichever is longer) before signing the informed consent form (ICF), is currently participating in another interventional treatment trial with an investigational agent or is using an investigational device at the time of Screening.

Conditions & Interventions

Interventions:
DRUG: cidofovir, DRUG: Brincidofovir
Conditions:
Adenovirus Infections
Keywords:
Brincidofovir, Cidofovir, Adenovirus, allo-HCT, BCV-PA02, ENOVIA

More Information

Description:
This randomized, open-label, parallel group, two-arm, multi-center assessment will compare IV BCV with IV CDV in adult and pediatric allogeneic HCT recipients with AdV viremia. A virologic response-driven approach to duration of treatment will be evaluated, in which randomized subjects are treated with either BCV or CDV until AdV viremia is confirmed as undetectable or until a maximum of 12 weeks of therapy, whichever occurs first. All subjects will be followed for a total of 24 weeks post-randomization, regardless of treatment assignment. Subjects will be assessed on a weekly basis through the end of treatment visit (EOT). Additional assessments will be performed at the test of cure (TOC) visit, which is 4 weeks after the last dose of study drug and at Weeks 12 and 24 post W1D1.

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