Treatment of Adenovirus (AdV) Infection in Allogeneic Hematopoietic Cell Transplant (HCT) Patients (pts) with Brincidofovir: 24 Week Interim Results from the AdVise Trial

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INTRODUCTION

AdV infection is an important cause of morbidity and mortality following HCT. In untreated HCT patients, the mortality rate of AdV infection is 25%, with 50% in patients with disseminated disease. There is no approved treatment for AdV infection or disease, although intravenous (IV) gamma globulin and cidofovir have been studied. Brincidofovir (BCV) has shown promise as a preemptive treatment in allogeneic HCT (allo HCT) patients with AdV infection.

METHODS

Study CMX301-204

Inclusion criteria:
- Within 30 days of, or up to 14 days post, HCT, undergoing preemptive therapy for AdV viremia or confirmed AdV disease
- Age ≥ 6 months

Exclusion criteria:
- Contraindication to BCV
- AdV DNA viremia >100,000 copies/mL
- History of cidofovir-induced bone marrow suppression

Study design:
- Single-arm, non-randomized, phase 2 study
- Patients were treated with 10 mg/kg BCV twice daily for 21 days
- AdV viremia and disease were monitored

RESULTS

- Efficacy:
  - AdV viremia was reduced by ≥ 2 log10 copies/mL in >90% of patients

- Safety:
  - BCV was well tolerated
  - GI, renal, and respiratory adverse events were reported

- Subgroup analysis:
  - Pediatric vs adult patients
  - HCT type

CONCLUSIONS

- BCV is a promising treatment for AdV infection in allo HCT patients
- Further studies are needed to confirm clinical efficacy and safety

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REFERENCES