A Phase 2a Study of IV BCV in Subjects With Adenovirus Infection

NCT04706923

Status	RECRUITING
Phase	Phase 2
Sponsor	SymBio Pharmaceuticals
Enrollment	52 participants

Key Eligibility Criteria

Inclusion (4)

- Male or female, aged 2 months and older at the time of informed consent.
- AdV DNA viremia \>10,000 copies/mL from a single sample, or 2 samples greater than 48 hours apart with the second result higher than the first and both greater than 1000 copies/mL, from the data obtained from the designated central virology laboratory of the local laboratory using the blood sample(s) collected informed consent has been obtained and within 7 days prior to Day 1 (AdV DNA viremia results collected within the 7 day window, but prior to consent may be used if the Informed Consent Form (ICF) signed by the subject provides approval) . CMV viremia with or without evidence of tissue invasive CMV disease. For laboratory results that are generated in units other than copies/mL or IU/mL, please refer to the testing laboratory for guidance on the appropriate conversion calculation.
- Either (a) have disseminated AdV disease or (b) have an underlying immunocompromised state, and have asymptomatic AdV infection or localized AdV disease.
- In the judgment of the investigator, be in a serious condition to be treated with intravenous cidofovir for AdV.

Exclusion (5)

- Subjects who weigh e120 kg.
- NIH/NCI CTCAE (United States \[US\] National Institutes of Health \[NIH\]/National Cancer Institute) Grade 2 or higher diarrhea (i.e., increase of e 4 stools per day over usual pre-transplant stool output) within 7 days prior to Day 1.
- NIH Stage 4 acute GVHD of the skin (i.e., generalized erythroderma with bullous formation) within 7 days prior to Day 1.
- NIH Stage 2 or higher acute GVHD of the liver function (i.e., bilirubin \>3 mg/dL \[SI: \>51 μmol/L\]) within 7 days prior to Day 1.
- NIH Stage 2 or higher acute GVHD of the gut (i.e., diarrhea \>556 mL/m2/day for pediatric subjects \[or \>1000 mL/day for young adults as applicable, at centers in the United States only\], or severe abdominal pain with or without ileus) within 7 days prior to Day 1.

Locations (11 total)

Research Site, Los Angeles, California, United States
Research Site, Los Angeles, California, United States
Research Site, San Francisco, California, United States
... and 8 more locations

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