

# Phase III DAS181 Lower Tract PIV Infection in Immunocompromised Subjects (Substudy: DAS181 for COVID-19): RCT Study

NCT03808922

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Status	RECRUITING
Phase	Phase 3
Sponsor	Ansun Biopharma, Inc.
Enrollment	274 participants

## Key Eligibility Criteria

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### Inclusion (19)

- At the time of randomization, requires supplemental oxygen e2 LPM due to hypoxemia.
- Immunocompromised, as defined by one or more of the following:
- Received an autologous or allogeneic hematopoietic stem cell transplantation (HSCT) at any time in the past
- Received a solid organ transplant at any time in the past
- Has been or is currently being treated with chemotherapy for hematologic malignancies (e.g., leukemia, myeloma, lymphoma) and/or solid tumor malignancies (e.g., lung, breast, brain cancer) at any time in the past
- ... and 14 more (see full listing online)

### Exclusion (17)

- Subjects may not be on hospice care or, in the opinion of the investigator, have a low chance of survival during the first 10 days of treatment
- Subjects with Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), or Alkaline Phosphatase (ALP) e3x ULN and Total Bilirubin (TBILI) e2x ULN Note: Subjects with ALT/AST/ALP e 3x ULN AND TB e2x ULN that have been chronically stable (for >1 year on more than one assessments) due to known liver pathology including malignancy (primary or metastasis), chronic medications, transplantation, or chronic infection will not be excluded
- Female subjects breastfeeding or planning to breastfeed at any time through 30 days after the last dose of study drug
- Subjects taking any other investigational drug used to treat pulmonary infection.
- Psychiatric or cognitive illness or recreational drug/alcohol use that, in the opinion of the principal investigator, would affect subject safety and/or compliance
- ... and 12 more (see full listing online)

## Locations (67 total)

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City of Hope cancer Center, Duarte, California, United States  
UCLA, Los Angeles, California, United States  
University of California Davis Health System, Sacramento, California, United States  
... and 64 more locations

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<https://clinicaltrials.gov/study/NCT03808922>

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