DAS181-3-01: A Phase III Randomized Placebo-Controlled Study to Examine the Efficacy and Safety of DAS181 for the Treatment of Lower Respiratory Tract Parainfluenza Infection in Immunocompromised Subjects

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: Not specified
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- needs supplemental oxygen ≥2 liters/minute due to low oxygen levels - immunocompromised, as defined by one or more of the following: received a stem cell transplant, organ transplant, 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, or has an immunodeficiency due to congenital abnormality - men and women of childbearing potential must use effective birth control - see link to clinical trials.gov for complete inclusion criteria

Exclusion Criteria:

- women who are pregnant or breastfeeding or planning to breastfeed at any time through 30 days after the last dose of study drug - taking any other investigational drug used to treat pulmonary infection - severe sepsis - see link to clincialtrials.gov for complete exclusion criteria

Conditions & Interventions

Interventions:
Drug: DAS181, Drug: DAS181 COVID-19, Drug: DAS181 OL, Drug: Placebo
Conditions:
Cancer, Respiratory System
Keywords:
Clinics and Surgery Center (CSC), Immune Compromised, Influenza, Lower Respiratory Tract Infection, Parainfluenza

More Information

Description: This research study is for participants who have a weakened immune system (are immunocompromised), have a lower lung infection and are currently using a machine or device to help them breathe. The study will look at whether the study drug, DAS181, works and how safe it is compared with a placebo in adults who have a weakened immune system (immunocompromised) and a parainfluenza virus (PIV) infection of the lower respiratory tract. A placebo looks the same as the study drug but does not contain any active ingredients.
Study Contact: Kristen Nickolas - nicko044@umn.edu
Principal Investigator: Jo-Anne Young, MD
Phase: PHASE3
IRB Number: STUDY00005735