A Phase 2 Multiple Dose Study to Evaluate the Efficacy and Safety of PUL-042 Inhalation Solution in Reducing Lower Respiratory Tract Complications in Patients with Hematologic Malignancies and Recipients of Hematopoietic Stem Cell Transplantation (HSCT) with Documented Viral Infections with Parainfluenza Virus (PIV), Human Metapneumovirus (hMPV) or Respiratory Syncytial Virus (RSV)

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- nasopharyngeal swab is positive for PIV, RSV, or hMPV (as a single pathogen or a mixed infection with rhinovirus) AND - diagnosis of a hematologic malignancies (i.e., leukemia, lymphoma, or multiple myeloma) or recipient of an allogeneic or autologous hematopoietic stem cell transplantation for one of the following diagnoses: leukemia, lymphoma, Hodgkin's lymphoma, non-Hodgkin's lymphoma, multiple myeloma, and myelodysplastic and myeloproliferative disorder - have undergone active chemotherapy within 6 months or are on an immunosuppressive therapy - symptomatic with upper or lower respiratory tract symptoms such as rhinorrhea, sore throat or cough - must not be pregnant, plan to become pregnant, or nurse a child during the study and through 30 days after completion of the study - see link to clinicaltrials.gov for complete Inclusion criteria

Exclusion Criteria:

- pulse oximetry of hemoglobin saturation less than 93% on room air - history of chronic pulmonary disease (e.g., asthma [including atopic asthma, exercise-induced asthma, or asthma triggered by respiratory infection], chronic pulmonary disease, pulmonary fibrosis, COPD), pulmonary hypertension, or heart failure - positive for other respiratory viruses (limited to influenza, SARS-CoV-2, adenovirus, or coronavirus) within 7 days - see link to clinicaltrials.gov for complete Exclusion criteria

Conditions & Interventions

Conditions:
Cancer, Respiratory System
Keywords:
Hematologic Malignancies, Hematopoietic Stem Cell Transplant (HSCT)

More Information

Description: The purpose of this research study is to see whether an experimental drug, PUL-042 Inhalation Solution (PUL-042), is effective in reducing the severity of lung infections in patients with hematologic malignancies and recipients of hematopoietic stem cell transplantation with viral infections due to PIV, hMPV, or RSV. Participants will receive PUL-042 or a placebo (an inactive agent that appears identical to PUL-042) through a nebulizer. This is a machine that uses a small motor to turn liquid into a mist, like a humidifier, so you can breathe the drug into your lungs. Participants will receive the experimental drug, PUL-042, or a placebo 3 times over a 6-day period.
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Phase: PHASE2
IRB Number: STUDY00023107