A Study of Rilematovir in Infants and Children and Subsequently in Neonates Hospitalized With Acute Respiratory Tract Infection Due to Respiratory Syncytial Virus (RSV)

Status: Recruiting

Eligibility Criteria

Age: Up to 5 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion criteria:

• The participant weighs within greater than or equal to (>=) 2.4 kilograms (kg) and less than or equal to (<=) 24.6 kg

• Each participant's parent(s) (preferably both if available or as per local requirements) or their legally acceptable representative(s) has/have signed an informed consent form (ICF) indicating that (s)he understands the purpose of, and procedures required for, the study; is willing for their child to participate in the study; with regards to the concomitant medication, the lifestyle consideration and study procedures and assessments to be performed by the parent(s)/caregiver(s) as well as those by the investigator/study site personnel

• The participant has an acute respiratory illness with at least 1 of the signs/symptoms within 24 hours prior to start of screening and at screening, as evaluated by the investigator in Upper respiratory tract infection: nasal congestion or rhinorrhea; and Lower respiratory tract infection: increased respiratory effort (as evidenced by subcostal, intercostal or tracheosternal retractions, grunting, head bobbing, nasal flaring, or tachypnea), wheezing, cough, cyanosis, or apnea; and systemic/general: feeding difficulties (defined as <75 percent [%] intake of normal food amounts); dehydration; fever; disturbed sleep, or disturbed activity level (irritable/restless/agitated/less responsive). Cough or wheezing cannot be the only LRTI sign/symptom present, that is, at least one other LRTI sign/symptom needs to be present for eligibility

• The time of onset of RSV signs/symptoms to the anticipated time of randomization must be less than or equal to (<=) 3 days. Onset of signs/symptoms is defined as the time of the day (or part of the day if time of the day cannot be specified) the parent(s)/caregiver(s) became aware of the first sign and/or symptom consistent with respiratory or systemic/general manifestation of signs/symptoms of RSV infection. The time of sign/symptom onset has to be assessed as accurately as possible

• Participants are otherwise healthy or have (a) risk factor(s) for severe RSV disease Exclusion criteria:

• The participant has had either confirmed severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) infection (test positive) during the four weeks prior to randomization, or close contact with a person with COVID-19 (test confirmed or suspected SARS CoV-2 infection) within 14 days prior to randomization

• Confirmed QT interval corrected for heart rate according to Fridericia's formula (QTcF) interval greater than (>) 450 milliseconds (msec) per the machine read parameter result at screening. Presence of an abnormal QTcF interval should be confirmed by repeat electrocardiogram (ECG) recording during screening

• Known personal or family history of Long QT Syndrome or sudden cardiac death

• Presence of repetitive ventricular premature contractions (>10/minutes [min]), second- or third-degree heart block, or complete or incomplete left bundle branch block, or complete right bundle branch block per the machine read ECG result at screening. Presence of any of the above abnormalities should be confirmed by repeat ECG recording during screening

Conditions & Interventions

Interventions:

Drug: Rilematovir, Drug: Rilematovir X mg/kg, Drug: Placebo

Conditions:

Respiratory Tract Infections

More Information

Contact(s): Study Contact - JNJ.CT@sylogent.com

Principal Investigator:

Phase: Phase 3

IRB

Number:

System ID: NCT04583280