A Surveillance Study of Susceptibility to Baloxavir Marboxil in Pediatric Participants With Influenza and Transmission of Influenza to Household Contacts

NCT06094010

Status	RECRUITING
Phase	Phase 3
Sponsor	Hoffmann-La Roche
Enrollment	750 participants

Key Eligibility Criteria

Inclusion (20)

- Participants with symptoms suggestive of influenza based on investigator's judgement with diagnosis confirmed by a positive local influenza test within 24 hours before full study screening
- Participants with a negative severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) test within 48 hours before full study screening
- Time interval between onset of influenza symptoms and the pre-dose examinations at screening is 48 hours or less
- \[A\] IP:
- Eligible to take part in Part A

... and 15 more (see full listing online)

Exclusion (11)

- Participants with severe influenza virus infection requiring inpatient treatment
- Severely immunocompromised participants \[including participants receiving immunosuppressant therapy, or those with cancer or human immunodeficiency virus (HIV) infection\] as defined by the investigator
- Participants with concurrent (non-influenza) infections requiring systemic anti-microbial and/or anti-viral therapy at the pre-dose examinations
- Treatment with baloxavir marboxil, peramivir, laninamivir, oseltamivir, zanamivir, rimantadine, umifenovir or amantadine within 30 days prior to screening
- Treatment with an investigational influenza-specific monoclonal antibody within 6 months or 5 half-lives, whichever is longer, prior to screening

... and 6 more (see full listing online)

Locations (51 total)

Central Alabama Research, Birmingham, Alabama, United States
Harrisburg Family Medical Center, Harrisburg, Arkansas, United States
Kendall South Medical Center Inc., Miami, Florida, United States
... and 48 more locations