ForPatients
by Roche

Influenza

Study to Assess the Safety, Pharmacokinetics, and Efficacy of Baloxavir Marboxil in Healthy Pediatric Participants From Birth to < 1 Year With Influenza-Like Symptoms

Trial Status	Trial Runs In	Trial Identifier
Completed	9 Countries	NCT03653364 2018-002154-70 CP40559

The clinical trial information herein is sourced from public registries such as ClinicalTrials.gov, EuClinicalTrials.eu, and ISRCTN.com. Additional patient-friendly (lay) content has been prepared by Roche to support understanding.

Official Title:

A Multicenter, Single-Arm, Open-Label Study to Assess the Safety, Pharmacokinetics, and Efficacy of Baloxavir Marboxil in Otherwise Healthy Pediatric Patients From Birth to < 1 Year With Influenza-Like Symptoms

Trial Summary:

This study will evaluate the safety, pharmacokinetics and efficacy of baloxavir marboxil in healthy pediatric participants from birth to <1 year with influenza like symptoms

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT03653364 2018-002154-70 CP40559
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 1 Year	No

Inclusion Criteria:

- Age from birth to < 1 year at screening
- Written informed consent for study participation obtained from participant's parents or legal guardian
- Parent/guardian willing and able to comply with study requirements, in the investigator's judgment

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- Participants with a diagnosis of influenza virus infection confirmed by the presence of all of the following:
- In the investigator's judgement there is a clinical suspicion of influenza 2. At least one respiratory symptom (either cough or coryza)

(b) Positive prescreening influenza test (RIDT or PCR) performed within 48 hours of screening

- Participants with a negative prescreening COVID-19 test (RAT or PCR) within 48 hours of screening
- The time interval between the onset of symptoms and screening is # 96 hours (the onset of symptoms is defined as the time when body temperature first exceeded 37.5°C if known, or the time when the first symptom was noticed by the parent or caregiver)

Exclusion Criteria:

- Hospitalized for complications of influenza or significant comorbidities
- Concurrent infections requiring systemic antiviral therapy at screening
- Require, in the opinion of the investigator, any of the prohibited medication during the study
- Preterm neonates (born at < 37 weeks gestation) and/or weighing < 2.5 kg at screening
- Previous treatment with peramivir, laninamivir, oseltamivir, zanamivir, or amantadine within 2 weeks prior to screening
- Immunization with a live/attenuated influenza vaccine during the 2 weeks prior to screening
- Concomitant treatment with steroids or other immuno-suppressant therapy
- Known HIV infection or other immunosuppressive disorder
- Uncontrolled renal, vascular, neurologic or metabolic disease (e.g., diabetes, thyroid disorders, adrenal disease), hepatitis, cirrhosis, or pulmonary disease or participants with known chronic renal failure
- Active cancer at any site
- History of organ transplant
- Known hypersensitivity to study drug (i.e., baloxavir marboxil) or to acetaminophen
- Participation in a clinical trial within 4 weeks or five half-lives of exposure to an investigational drug prior to screening, whichever is longer

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