

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**  
Completed

**Trial Runs In**  
9 Countries

**Trial Identifier**  
NCT03653364 2018-002154-70  
CP40559

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

### 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**  
All

**Age**  
# 1 Year

**Healthy Volunteers**  
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
- Participants with a diagnosis of influenza virus infection confirmed by the presence of all of the following:

# ForPatients

*by Roche*

- In the investigator's judgement there is a clinical suspicion of influenza
- 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  $\leq 96$  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