ForPatients
*by Roche*

Influenza

# Study to Assess the Safety, Pharmacokinetics, and Efficacy of Baloxavir Marboxil in Chinese Pediatric Participants 1 to <12 Years of Age With Influenza Symptoms

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Recruiting | 1 Country | NCT06774859 YV44465 |

*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 Phase III, Randomized, Open-Label, Active-Controlled Study to Assess the Safety, Pharmacokinetics, and Efficacy of Baloxavir Marboxil in Chinese Pediatric Patients 1 to <12 Years of Age With Influenza Symptoms

## *Trial Summary:*

The purpose of this study is to evaluate the safety of a single dose baloxavir marboxil compared with 5 days of oseltamivir administered twice a day (BID) in Chinese pediatric participants aged 1 to < 12 years with influenza symptoms.

| Hoffmann-La Roche | Phase 3 |
|---|---|
| Sponsor | Phase |

**NCT06774859 YV44465**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| All | #1 Year & # 11 Years | No |

## *Inclusion Criteria:*

- A participant who has a diagnosis of influenza virus infection and meets all the following conditions:
- Fever # 38°C (tympanic temperature) at screening
- At least one of the respiratory symptoms of influenza virus infection
- A rapid influenza diagnostic test (RIDT) or polymerase chain reaction (PCR) shows positive for influenza A/B, e.g., point-of-care/local laboratory results with use of nasal aspirate, throat swab, or nasal drip/droplet (or other appropriate sample)

- The time interval between the onset of symptoms and screening is # 48 hours
- PCR (-) or antigen test (-) for severe acute respiratory virus-coronavirus 2 (SARS-CoV-2) using point-of-care/local laboratory test with nasal aspirate, throat swab, or nasal drip/droplet (or other appropriate sample)

## *Exclusion Criteria:*

- A participant having severe influenza virus infection symptoms requiring inpatient treatment
- Received systemic corticosteroid or immunosuppressive therapy
- Primary immunodeficiency syndrome
- History of organ transplantation
- Human immunodeficiency virus (HIV) infection
- Immunization with a live/attenuated influenza vaccine in 2 weeks prior to randomization
- Previous malignancy within the last 5 years or has an active cancer at any site
- A participant who received any medications with anti-flu effect such as baloxavir, peramivir, oseltamivir, zanamivir, favipiravir, arbidol, amantadine or traditional Chinese anti-influenza medicines within 30 days before screening
- Diagnosed with or suspected SARS-CoV-2 infection, or close contacts of diagnosed or suspected SARS-CoV-2 infected patients
- Severe underlying disease or condition potentially affecting study evaluation in the opinion of the investigator/sub-investigator
- A participant who received an investigational or unapproved drug product within 30 days or 5 x the half-life before screening, whichever is longer