ForPatients
by Roche

Influenza

A Study to Confirm Efficacy of a Single Dose of Baloxavir Marboxil in the Post-exposure Prophylaxis (PEP) of Influenza Virus Infection in Chinese Participants

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07827599 YV46459

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, Double-blinded, Placebo-controlled Study to Confirm Efficacy of a Single Dose of Baloxavir Marboxil in the Post-exposure Prophylaxis of Influenza Virus Infection in Chinese Participants

Trial Summary:

The main purpose of the study is to evaluate the efficacy of a single dose of baloxavir marboxil compared with placebo in the PEP of influenza virus infection with respect to symptomatic, laboratory-confirmed influenza in participants who are household contacts (HHCs) of participants with influenza (index participants).

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT07827599 YV46459
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#5 Years	Accepts Healthy Volunteers

Inclusion Criteria:

Index Participants (Participants With Influenza Virus Infection):

- First participant in a household with influenza virus infection in the current influenza season
- Fewer than 6 HHCs

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- Agreement by all household members to participate in the study and comply with the study protocol for the duration of the study
- Diagnosed as having influenza with positive rapid influenza diagnostic test (RIDT) or polymerase chain reaction (PCR) result
- Onset of symptoms within 48 hours or less at time of signing Informed Consent Form (ICF)/Assent Form
- PCR (-) or antigen test (-) for severe acute respiratory virus-coronavirus 2 (SARS-CoV-2) using point-of-care or local laboratory test

HHCs of Index Participants:

- Lived with the index participant for 48 hours or more prior to informed consent/assent
- Meet all the following criteria and are judged not to have influenza virus infection by the investigator: body temperature (tympanic) <37.5 degrees Celsius (°C); no influenza-like symptoms (cough, sore throat, headache, nasal discharge/nasal congestion, feverishness or chills, muscle or joint pain, or fatigue) at screening; negative RIDT or PCR result for influenza
- For participants 12 years of age or older, ability to evaluate influenza symptoms by using a participant influenza symptoms diary; For participants under 12 years of age, capability of parents/caregivers to evaluate influenza symptoms by using a participant influenza symptoms diary
- PCR (-) or antigen test (-) for SARS-CoV-2 using point-of-care or local laboratory test

Exclusion Criteria:

HHCs of Index Participants:

- Diagnosed with influenza during the current influenza season
- Unable to live with the index patient from screening until Day 10
- Live with a household member who has any influenza-like symptom(s) other than the index participant on the day of screening
- Live with household members other than the index participant who was diagnosed with or strongly suspected to have influenza during the current influenza season
- Have any underlying diseases requiring systemic (oral or injection), or nasal treatment of antipyretics/ analgesics, corticosteroids, or immunosuppressive agents
- Immunocompromised
- Use of any medications with anti-influenza effect within 30 days prior to screening
- Known allergy and/or history of significant intolerance against baloxavir marboxil
- Exposure to an investigational drug within 30 days or 5 half-lives of the drug prior to screening, whichever is longer

Note: Other protocol-defined inclusion/exclusion criteria may apply

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