ForPatients
*by Roche*

Influenza

# Study to Assess Efficacy and Safety of Baloxavir Marboxil In Combination With Standard-of-Care Neuraminidase Inhibitor In Hospitalized Participants With Severe Influenza

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Completed | 28 Countries | NCT03684044 2018-001416-30 CP40617 |

*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-Blind Placebo-Controlled, Multicenter Study To Evaluate the Efficacy and Safety of Baloxavir Marboxil in Combination With Standard-of-Care Neuraminidase Inhibitor in Hospitalized Participants With Severe Influenza

## *Trial Summary:*

This study will evaluate the efficacy, safety, and pharmacokinetics of baloxavir marboxil in combination with a standard-of-care (SOC) neuraminidase inhibitor (NAI) (i.e., oseltamivir, zanamivir, or peramivir) compared with a matching placebo in combination with a SOC NAI in hospitalized patients with influenza.

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

**NCT03684044 2018-001416-30 CP40617**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| All | # 12 Years | No |

## *Inclusion Criteria:*

- Adult participants: Signed informed consent by any participant capable of giving consent, or, where the participant is not capable of giving consent, by his or her legal/authorized representative

- Adolescent participants not able to legally consent: written informed consent for study participation is obtained from participant's parents or legal guardian, with assent as appropriate by the participant, depending on the participant's level of understanding and capability to provide assent
- Participants who require hospitalization for severe influenza or acquire influenza during hospitalization, the severity of which requires an extension of hospitalization
- Diagnosis of influenza A and/or B by a positive Rapid Influenza Diagnostic Test (RIDT) or reverse transcriptase-polymerase chain reaction (RT-PCR)
- The time interval between the onset of symptoms and randomization is within 96 hours
- A score of #4 based on the National Early Warning Score 2 (NEWS2)
- Participants will require objective criteria of seriousness defined by at least one of the following criteria:
- Requires ventilation or supplemental oxygen to support respiration
- Has a complication related to influenza that requires hospitalization (e.g., pneumonia, central nervous system involvement, myositis, rhabdomyolysis, acute exacerbation of chronic kidney disease, asthma or chronic obstructive pulmonary disease (COPD), severe dehydration, myocarditis, pericarditis, exacerbation of ischemic heart disease)
- For women of childbearing potential: Agreement to remain abstinent or use contraceptive methods with a failure rate of < 1% per year during the treatment period and for 28 days after the last dose of study treatment. Hormonal contraceptive methods must be supplemented by a barrier method.

## *Exclusion Criteria:*

- Participants who have received more than 48 hours of antiviral treatment for the current influenza infection prior to screening
- Participants who have received baloxavir marboxil for the current influenza infection
- Known contraindication to neuraminidase inhibitors
- Participants hospitalized for exclusively social reasons (e.g., lack of caregivers at home)
- Participants expected to die or be discharged within 48 hours, according to the investigator's judgement
- Participants weighing < 40 kg
- Participants with known severe renal impairment (estimated glomerular filtration rate < 30 mL/min/1.73 m2) or receiving continuous renal replacement therapy, hemodialysis, peritoneal dialysis
- Participants with any of the following laboratory abnormalities detected within 24 hours prior to or during screening (according to local laboratory reference ranges:
- Alanine Transaminase (ALT) or Aspartate Transaminase (AST) level > 5 times the upper limit of normal (ULN) OR
- ALT or AST > 3 times the ULN and total bilirubin level > 2 times the ULN
- Pregnant or breastfeeding, or positive pregnancy test in a predose examination, or intending to become pregnant during the study or within 28 days after the last dose of study treatment
- Exposure to an investigational drug within 5 half-lives or 30 days (whichever is longer) of randomization
- Any serious medical condition or abnormality in clinical laboratory tests that, in the investigator's judgment, precludes the participant's safe participation in and completion of the study
- Known hypersensitivity to baloxavir marboxil or the drug product excipients