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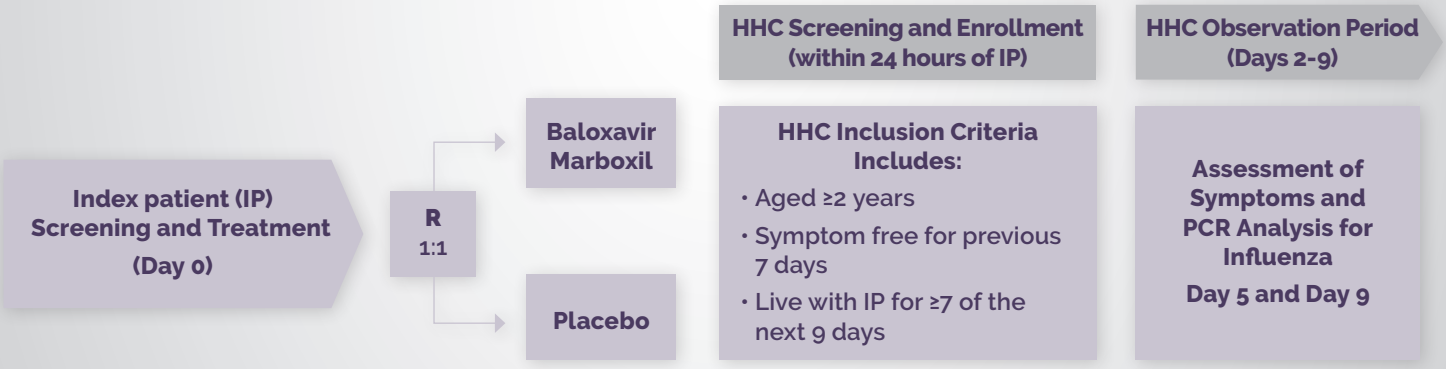
# NOW ENROLLING CENTERSTONE

## *INFLUENZA ONWARD TRANSMISSION STUDY*

- A Phase IIIB, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Clinical Efficacy Study of Baloxavir Marboxil for the Reduction of Direct Transmission of Influenza From Otherwise Healthy Patients to Household Contacts (HHC)

**Study to Assess the Efficacy of Baloxavir Marboxil Versus Placebo to Reduce Onward Transmission of Influenza A or B in Households**




## *HOW TO ENROLL A PATIENT*

**FOR MORE INFORMATION, PLEASE CONTACT:**

**Reference Study ID Number: MV40618**
888-662-6728 (United States only)
global-roche-genentech-trials@gene.com
https://www.centerstoneflutrial.com/en-us/index.html

**Reference:** Study to assess the efficacy of baloxavir marboxil versus placebo to reduce onward transmission of influenza A or B in households. ClinicalTrials..gov identifier: NCT03969212. Updated August 5, 2021. Accessed August 27, 2021. https://clinicaltrials.gov/ct2/show/NCT03969212

The product reference is presented only for the purpose of providing an overview of the clinical trial and should not be construed as a recommendation for use of the product for unapproved uses.

For more information on trial inclusion and exclusion criteria or enrolling sites, visit www.clinicaltrials.gov.

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**IP screened**
(doctor visit/clinic)

- Aged ≥5 and ≤64 years
- OwH
- Influenza positive by POC for influenza A or B **AND:**
  - Fever*
  - **OR**
  - Any influenza symptoms†
- PCR (-) or antigen test (-) for SARS-CoV-2
- Symptoms ≤48 hours
- ≥2 eligible HHCs

*IP receives baloxavir marboxil*

**R‡**

*IP receives placebo*

**Blinded household is screened and observed**

**HHC screened§**

- Aged ≥2 years
- Influenza negative by POC for influenza A/B based on respiratory swab within **24 hours** of the IP's treatment
- PCR (-) or antigen test (-) for SARS-CoV-2
- No influenza symptoms within 7 days prior to screening¶
- Temperature <38.0 °C (tympanic)
- In household for ≥7 of the next 9 days

**HHC observation period**

- HHCs with symptoms before Day 5 may be tested for primary endpoint
- If POC+, then treat as per local standard of care

IP: respiratory swab and AEs Days 3 and 5

**Primary endpoint assessment**

- HHCs receive respiratory swab

**Primary endpoint:**

- PCR+ HHC within 5 days after study drug administration

IP: respiratory swab and AEs

**HHC observation period**

- HHCs with symptoms before Day 9 may be tested for secondary endpoint
- If PCR+, then treat as per local standard of care

**Secondary endpoint assessment**

- HHCs receive respiratory swab

**Secondary endpoint:**

- PCR+ HHC

IP: respiratory swab and AEs

| Day 0 | Days 1-5 | Day 5 | Days 6-8 | Day 9# |
|---|---|---|---|---|

## STUDY ENDPOINTS

- **Primary endpoint:** percentage of HHCs with positive PCR and same virus subtype as IP within 5 days
- **Select secondary endpoints:** symptomatic HHCs with PCR-confirmed influenza at Day 9, PCR-positive HHCs, safety, health economic endpoints

## KEY EXCLUSION CRITERIA

**INDEX PATIENT**

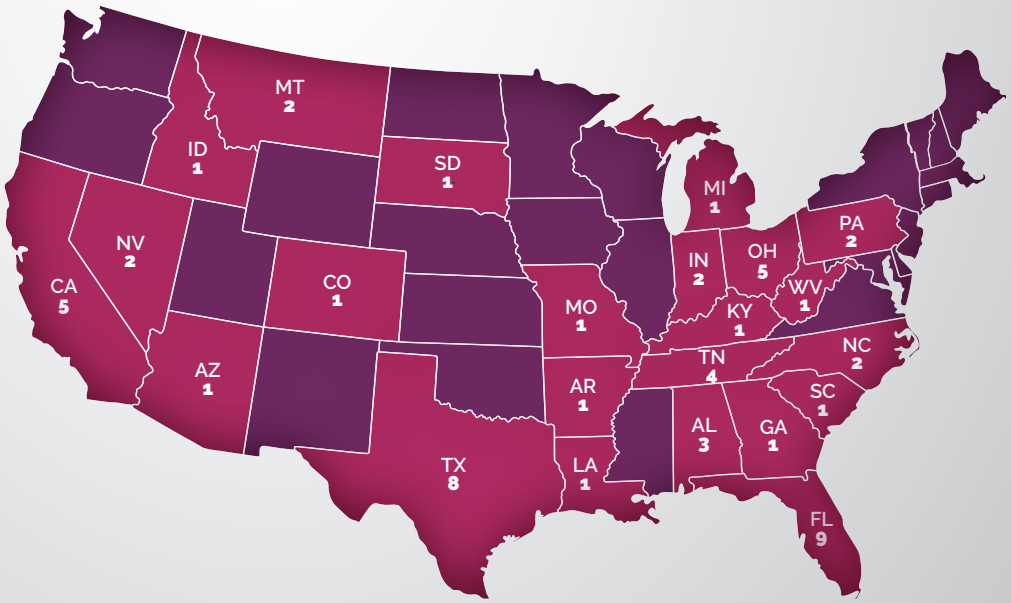
- Severe influenza requiring hospitalization

**HOUSEHOLD CONTACTS**

- Influenza diagnosis within previous 6 months
- Immunocompromised, pregnant, or within 2 weeks postpartum

AEs = adverse events; IP = index patient; OwH = otherwise healthy; PCR = polymerase chain reaction; POC = point of care.
*≥38.0˚C per tympanic or rectal thermometer; ≥37.5˚C per axillary, oral, or forehead/temporal thermometer; †Cough, sore throat, nasal congestion, headache, feverishness or chills, muscle or joint pain, and fatigue; ‡Stratification factors: age, household size, region, and time since symptom onset; §HHC screening must start within 24 hours of IP randomization and may occur on IP study Day 0 or 1; ¶Symptoms for HHC aged ≥12 years: cough, sore throat, nasal congestion, headache, feverishness or chills, muscle or joint pain, and fatigue; symptoms for HHC aged ≥2 to <12 years: cough, nasal congestion, or rhinorrhea; #IPs aged <12 years will have a safety follow-up visit on Day 21 (+2 days).

## Locations of Enrolling Sites*




*The list of study sites is expanding.

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