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NOW ENROLLING

miniSTONE 1

Baloxavir Marboxil in Healthy Pediatric Patients

miniSTONE 1: 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

INCLUSION CRITERIA INCLUDES:

- Influenza diagnosis;
  - Fever ≥38°C
  - ≥1 respiratory symptom(s)
- ≤96 hours from symptom onset

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ONE SINGLE DOSE OF BALOXAVIR MARBOXIL BASED ON BODY WEIGHT AND AGE

→

SAFETY FOLLOW-UP PERIOD

29 days

HOW TO ENROLL A PATIENT

FOR MORE INFORMATION, PLEASE CONTACT:

Reference Study ID Number: CP40559
888-662-6728 (United States only)
global-roche-genentech-trials@gene.com
https://www.gene.com/medical-professionals/clinical-trial-information

Reference: Study to assess the safety, pharmacokinetics, and efficacy of baloxavir marboxil in healthy pediatric participants from birth to < 1 year with influenza-like symptoms. ClinicalTrials.gov identifier: NCT03653364. Updated August 5, 2021. Accessed August 25, 2021. https://clinicaltrials.gov/ct2/show/NCT03653364

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, and study locations, visit www.clinicaltrials.gov.

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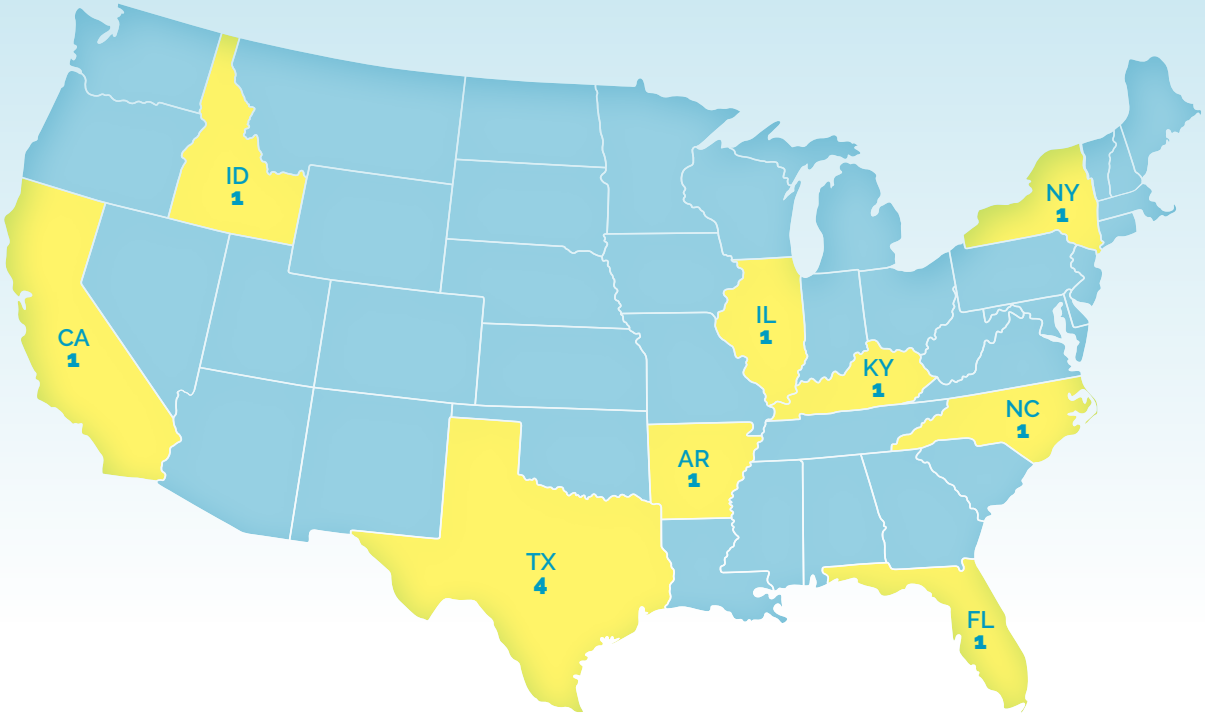
STUDY ENDPOINTS

- **Safety (primary):** Percentage of participants with adverse events and serious adverse events
- **Select secondary:** Pharmacokinetics, virological, and clinical efficacy (TTAS)

KEY EXCLUSION CRITERIA

- Hospitalized for complications of influenza
- Significant comorbidities
- Preterm neonates (born at <37 weeks gestation and/or weighing <2.5 kg at screening)

LOCATIONS OF ENROLLING SITES*



*The list of study sites is expanding.

TTAS = time to alleviation of symptoms.

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