A secondary data use study of pregnancy and infant outcomes following administration of casirivimab + imdevimab (Ronapreve, REGEN-COV) during pregnancy based on data obtained from the COVID-19 international drug pregnancy registry [COVID-PR]

First published: 05/11/2021

Last updated: 28/04/2025

Study | Discontinued

Administrative details

EU PAS number

EUPAS43694

Study ID

46116

DARWIN EU® study

No

Study countries

- [ ] Algeria
- [ ] Argentina
- [ ] Australia
- [ ] Austria
- [ ] Bahrain
- [ ] Belgium
- [ ] Brazil
- [ ] Bulgaria
- [ ] Cameroon
- [ ] Canada
- [ ] Chile
- [ ] Colombia
- [ ] Croatia
- [ ] Denmark
- [ ] Dominican Republic
- [ ] Ecuador
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Ghana
- [ ] Greece
- [ ] Guadeloupe
- [ ] Guam
- [ ] Guatemala
- [ ] Hungary
- [ ] India
- [ ] Iran, Islamic Republic of
- [ ] Ireland
- [ ] Israel

- [ ] Italy
- [ ] Kenya
- [ ] Latvia
- [ ] Lebanon
- [ ] Lithuania
- [ ] Malawi
- [ ] Mauritius
- [ ] Mexico
- [ ] Monaco
- [ ] Namibia
- [ ] Netherlands
- [ ] Nigeria
- [ ] Pakistan
- [ ] Paraguay
- [ ] Peru
- [ ] Philippines
- [ ] Poland
- [ ] Portugal
- [ ] Puerto Rico
- [ ] Romania
- [ ] Russian Federation
- [ ] Réunion
- [ ] Saudi Arabia
- [ ] Senegal
- [ ] Singapore
- [ ] South Africa
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] Tunisia

- [ ] Türkiye
- [ ] Ukraine
- [ ] United Arab Emirates
- [ ] United Kingdom (Northern Ireland)
- [ ] United States
- [ ] Uruguay
- [ ] Zambia

Study description

This study uses data collected from the COVID-19 International Drug Pregnancy Registry (COVID-19 PR) to 1) provide descriptive analysis of pregnancy and infant outcomes in patients treated with casirivimab + imdevimab, and 2) provide descriptive analysis of pregnancy and infant outcomes for casirivimab + imdevimab against comparator groups consisting of pregnant women that were hospitalized but not treated with a medication specifically indicated for the treatment of mild to severe COVID-19.

Roche, the Marketing Authorization Holder (MAH), terminated participation in the COVID-PR and associated GA43744 study in May 2024 due to low enrollment associated with diminished in vitro neutralizing potency of casirivimab + imdevimab against Omicron subvariants.
Due to a lack of data, no secondary data analyses were performed.
Official cancellation of this study was initiated on 2 August 2024.

Study status

Discontinued

Research institutions and networks

Institutions

Pregistry

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Vincent Yau global.clinical_trial_registry@roche.com

Study contact

global.clinical_trial_registry@roche.com

Primary lead investigator

Vincent Yau

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/11/2021

Actual: 15/02/2022

Study start date

Planned: 02/11/2021

Actual: 15/02/2022

Date of final study report
Planned: 01/12/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

F. Hoffmann-La Roche Ltd

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Other study registration identification numbers and links

GA43744

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The main objective of the study is to evaluate the effect that medications indicated for the treatment of mild to severe COVID-19 have on obstetric, neonatal, and infant outcomes.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

RONAPREVE

Study drug International non-proprietary name (INN) or common name

CASIRIVIMAB

IMDEVIMAB

Anatomical Therapeutic Chemical (ATC) code

(J06BD07) casirivimab and imdevimab

casirivimab and imdevimab

Medical condition to be studied

COVID-19

Pregnancy

Population studied

Age groups

- Neonate
  - Preterm newborn infants (0 – 27 days)
  - Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Adults (18 to < 65 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

200

Study design details

Outcomes

Obstetric outcomes (e.g. miscarriage, stillbirth, neonatal death, maternal death, preterm delivery, etc.), neonatal outcomes (e.g. major congenital malformations, low birth weight, small for gestational age, etc.), and infant outcomes until 1 year of age (e.g. developmental milestones) and maternal outcomes (e.g. COVID-19 reinfection). Descriptive analysis of pregnancy and infant outcomes for Cas/Imd against comparator groups consisting of pregnant women treated with another therapy for mild to severe COVID-19 (active comparator), and pregnant women hospitalized but not treated with a medication specifically indicated for the treatment of mild to severe COVID-19 (unexposed comparator for hospitalized exposed patient).

Data analysis plan

Descriptive statistics will be used to summarize overall frequency of selected adverse pregnancy outcomes, as well as frequencies of specific outcomes such as major congenital malformations, miscarriages, stillbirths, preterm deliveries, small for gestational age infants, maternal obstetric and postpartum health, admission into the neonatal Intensive Care Unit (ICU), infant developmental milestones (at 6, 9, and 12 months of age), neonatal death and infant death, and maternal and infant incidence of COVID-19.

Summary results

The MAH terminated participation in the COVID-PR and associated GA43744 study in May 2024 due to low enrollment associated with diminished in vitro neutralizing potency of casirivimab + imdevimab against Omicron subvariants. Due to a lack of data, no secondary data analyses were performed; hence, there are no results to report. Official cancellation of this study was initiated on 2 August 2024.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Disease registry

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No