

## TERIS Summary

TERIS Agent Number: 6845 Bibliographic Search Date: 12/2022  
Agent Name: **CASIRIVIMAB / IMDEVIMAB**

Casirivimab/Imdevimab (casirivimab and imdevimab) is a combination of two neutralizing monoclonal antibodies that target the SARS-CoV-2 spike protein. Casirivimab/Imdevimab is administered intravenously in the treatment of COVID-19.

---

**Magnitude of Teratogenic Risk to Child Born After Exposure During Gestation:** UNDETERMINED

**Quality and Quantity of Data on Which Risk Estimate is Based:** LIMITED

**Comments:** BECAUSE CASIRIVIMAB/IMDEVIMAB IS AN ANTIBODY MIXTURE, IT MAY BE ACTIVELY TRANSPORTED ACROSS THE PLACENTA IN LATER PREGNANCY.

---

### Summary of Teratology Studies:

#### MAJOR CONGENITAL ANOMALIES

No epidemiological studies of congenital anomalies among infants born to women who were treated with casirivimab and imdevimab during pregnancy have been reported.

No congenital anomalies were described in a term infant born to a mother with COVID-19 who received casirivimab and imdevimab at the end of her pregnancy (Mayer et al., 2021). This infant was admitted, however, to the neonatal intensive care unit with intermittent tachypnea but was discharged at day 2 after delivery. No congenital anomalies were identified on ultrasound or at the time of delivery among four pregnancies in women who were infused with casirivimab and imdevimab at gestational ages ranging between 11 and 32 weeks (Hirshberg et al., 2021).

#### ADVERSE PREGNANCY AND NEONATAL OUTCOMES

No significant differences in the frequency of adverse pregnancy or neonatal outcomes were reported among 24 (12 undelivered) women who received casirivimab and imdevimab at some point in their pregnancy when compared to 47 (three undelivered) untreated women who were hospitalized for COVID-19 during pregnancy in a retrospective cohort study (Levey et al., 2022).

In seven pregnant patients with COVID-19 who received casirivimab and imdevimab, five delivered healthy infants (two had pre-emptive caesarian section at 31 and 36 weeks) while two had uncomplicated ongoing pregnancies (Folkman et al., 2022). In a separate case series of 24 women infused with casirivimab and imdevimab for COVID-19 treatment during pregnancy, 23 delivered healthy neonates, while one resulted in fetal death (Thilagar et al., 2022). No details on timing of exposure were provided in this series. Fetal growth restriction in two term infants whose mothers received casirivimab and imdevimab in pregnancy was reported in another case-series of 14 exposed pregnancies (Richley et al., 2022). In another case-series of 13 hospitalized COVID-19 patients who received casirivimab and imdevimab in the second half of pregnancy, two of four patients delivered via caesarian section and were preterm while nine pregnancies were still ongoing with no complications at the time of publication (Buonomo et al., 2022).

#### ANIMAL TERATOLOGY STUDIES

Animal teratology studies of casirivimab and imdevimab conducted by the manufacturer have not been published in the peer-reviewed literature.

#### Selected References:

(Each paper is classified as a review [R], human case report [C], human epidemiological study [E], human clinical series [S], animal study [A], or other [O].)

Buonomo AR, Saccone G, Esposito N, Di Filippo I, Pinchera B, Foggia M, Zappulo E, Giaccone A, Schiano Moriello N, Viceconte G, Scotto R, Bifulco G, Gentile I: Casirivimab and imdevimab for pregnant women hospitalized for severe coronavirus disease 2019 (COVID-19). *Am J Perinatol* 2022 Aug 16 (published online ahead of print). [S]

Folkman R, Blennow O, Tovatt T, Pettersson K, Nowak P: Treatment of COVID-19 with monoclonal antibodies casirivimab and imdevimab in pregnancy. *Infection* 2022 Apr 28 (published online ahead of print). [S]

Hirshberg JS, Cooke E, Oakes MC, Odibo AO, Raghuraman N, Kelly JC: Monoclonal antibody treatment of symptomatic COVID-19 in pregnancy: initial report. *Am J Obstet Gynecol* 225(6):688-689, 2021. [C]

Levey NH, Forrest AD, Spielman DW, Easley KA, Dude CM, Badell ML: Outcomes of pregnant patients treated with REGEN-COV during the COVID-19 pandemic. *Am J Obstet Gynecol MFM* 4(5):100673, 2022. [E]

Mayer C, VanHise K, Caskey R, Naqvi M, Burwick RM: Monoclonal antibodies casirivimab and imdevimab in pregnancy for coronavirus disease 2019 (COVID-19). *Obstet Gynecol* 138(6):937-939, 2021. [C]

Richley M, Rao RR, Afshar Y, Mei J, Mok T, Vijayan T, Weinstein S, Pham CU, Madamba J, Shin CS, Suda D, Han CS: Neutralizing monoclonal antibodies for coronavirus disease 2019 (COVID-19) in pregnancy: a case series. *Obstet Gynecol* 139(3):368-372, 2022. [S]

Thilagar BP, Ghosh AK, Nguyen J, Theiler RN, Wick MJ, Hurt RT, Razonable RR, Ganesh R: Anti-spike monoclonal antibody therapy in pregnant women with mild-to-moderate coronavirus disease 2019 (COVID-19). *Obstet Gynecol* 139(4):616-618, 2022, 2022. [S]