

TERIS Summary

TERIS Agent Number: 6847 Bibliographic Search Date: 12/2022
Agent Name: **SOTROVIMAB**

Sotrovimab is an investigational human neutralizing monoclonal antibody with activity against SARS-COV-2. Sotrovimab is administered intravenously in the treatment of mild to moderate 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: VERY LIMITED

Comments: BECAUSE SOTROVIMAB IS AN ANTIBODY, 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 sotrovimab during pregnancy have been reported.

ADVERSE PREGNANCY AND NEONATAL OUTCOMES

No adverse fetal or pregnancy-related complications were reported in a COVID-19 positive patient who had received sotrovimab in the second trimester of pregnancy and followed two months post-infusion (Gupta & Arguello Perez 2022). In another case report, a low birth weight, but otherwise healthy, infant was delivered prematurely at 35 weeks gestation to a kidney-transplant mother, who was on multiple transplant medications, and administered sotrovimab on gestational week 27 due to COVID-19 illness (Alkindi et al., 2022).

ANIMAL TERATOLOGY STUDIES

Animal teratology studies of sotrovimab 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].)

AlKindi F, Chaaban A, Al Hakim M, Boobes Y: Sotrovimab use for COVID-19 infection in pregnant kidney transplant recipient. *Transplantation* 106(5):e277-e278, 2022. [C]

Gupta I, Arguello Perez ES: Use of sotrovimab in a pregnant patient with COVID-19 infection. *Cureus* 14(2):e22658, 2022. [C]