35. Pregnancy associated adverse events in patients treated with therapies for COVID-19 reported to the FDA ACMT COVID-19 ToxIC (FACT) pharmacovigilance project

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Background: The COVID-19 pandemic prompted an unprece- dented surge in repurposing and developing available pharmaceut- icals and therapies for approved and unapproved prophylaxis or treatment of the SARS-CoV-2 virus. Due to variations in physiology and fetal risk, pregnant patients are often excluded from pharma- ceutical efficacy and safety studies. Therefore, this population is vul- nerable to adverse events (AEs) from such therapies.

Methods: This is a case series of AEs in pregnant patients associ- ated with therapies for COVID-19 submitted to the FDA ACMT COVID-19 ToxIC (FACT) Pharmacovigilance Project between November 23, 2020 to April 14, 2022. FACT is an active surveil- lance project with 17 geographically distinct participating med- ical centers focusing on identifying possible AEs related to any medication or substance administered by a provider or patient with the intent to treat or prevent COVID-19 infection. Cases are identified via site-specific mechanisms, including direct contact, provider self-referral, pharmacist referral, or chart review. The inclusion criteria in this subset analysis included pregnant patients with suspected AEs after a COVID-19 therapy.

Results: Of the 263 cases reported to FACT during the study period, 24 (9.1%) of the cases were suspected AEs in pregnant patients. The majority of these AEs were in patients exposed to monoclonal anti- body (mAb) treatments for COVID-19. Black/African patients com- prised 9 (38%) of cases of AEs. One case was of a patient who developed hepatotoxicity from supratherapeutic acetaminophen use to treat COVID-19 symptoms. The most common effects were gastro- intestinal, but patients developed a wide range of AEs. In 14 cases, the provider filled out the FACT Pharmacovigilance Projects' Pregnancy and Fetal Supplemental Data Collection Form, which pro- vided further details specific to the patient's obstetric history. This dataset revealed six patients who required emergency cesarean sec- tions, five of which were due to fetal distress and one for maternal factors. Overall, while there were zero deaths, there were multiple cases deemed to have life-threatening reactions, requiring interven- tion, or necessitating a higher level of care.

Conclusions: The FACT Pharmacovigilance Project was created as a novel multi-site pharmacosurveillance program to monitor real-world AEs related to therapies utilized for the prophylaxis and treatment of COVID-19. Pregnant patients represent a high- risk group often excluded from medical

trials. This data displays AEs which occurred in response to COVID-19 therapies. Further study and analysis will be needed to evaluate the effects of these therapies on the development of fetal distress and congenital anomalies. This project is ongoing and will continue to identify ADEs associated with COVID-19-related therapeutics.