FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Obstetrics, Reproductive and Urologic Drugs Advisory Committee Hearing
October *17* - *19*, 2022

QUESTIONS

Makena

Sponsor: Covis Pharma Group/Covis Pharma GmbH

INDICATION:

- To reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.

1. **FOR DISCUSSION AND VOTE:**

   Do the findings from Trial 003 verify the clinical benefit of Makena on neonatal morbitity and mortality from complications of preterm birth?

2. **FOR DISCUSSION AND VOTE:**

   Does the available evidence demonstrate that Makena is effective for its approved indication of reducing the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth?

3. **FOR DISCUSSION**

   Should FDA allow Makena to remain on the market? As part of that discussion, you may discuss:
   - whether the benefit-risk profile supports retaining the product on the market;
   - what types of studies could provide confirmatory evidence to verify the clinical benefit of Makena on neonatal morbidity and mortality from complications of preterm birth?

   FOR VOTE:

   Considering your responses to the previous questions both in the discussions and votes, should FDA allow Makena to remain on the market while an appropriate confirmatory study is designed and conducted?