Evaluation of Drugs for the Treatment of Chronic HCV Infection in Pregnant Women: FDA Perspective

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Elimination of Perinatal HBV and HCV Transmission: New opportunities to improve screening, prevention and care
Coalition for Global Hepatitis Elimination
The Task Force for Global Health
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• No conflicts of interest
• This presentation reflects the views of the speaker and should not be construed to represent FDA views or policies
Considerations for Pregnancy Studies

Premarketing
To support clinical trials (and marketing authorization) in pregnant subjects for small molecule pharmaceuticals, as outlined in ICH M3(R2):

• Conduct the standard battery of genotoxicity tests
• Assess the nonclinical developmental and reproductive toxicity (DART) as outlined in ICH S5(R3):
  – Fertility and Early Embryonic Development (FEED) to Implantation (Segment I)
  – Embryo-Fetal Development (EFD) in 2 species (Segment II)
  – Prenatal and Postnatal Development (PPND), Including Maternal Function (Segment III)

Postmarketing
• Opportunistic pharmacokinetic (PK) studies among patients already receiving the treatment
  – To ensure adequate systemic exposure in pregnancy as exposure could be affected by the physiologic changes during pregnancy
  – Safety data in nonpregnant adults is sufficient to allow opportunistic PK/safety studies in pregnant women
  – Goal is to explore and confirm doses for use during pregnancy that will lead to exposures comparable to the observed data in nonpregnant adults
  – Potential sources to collect safety data
    o Pregnancy exposure registries, population-based surveillance, electronic data sources (e.g., insurance claims, electronic health records)
    o Other pharmacovigilance methods – case reports and case series
Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products — Content and Format Guidance for Industry

IV. SPECIFIC SUBSECTIONS

A. 8.1 Pregnancy

1. Pregnancy Exposure Registry
2. Risk Summary
   a. Risk statement based on human data
   b. Risk statement based on animal data
   c. Risk statement based on pharmacology
3. Clinical Considerations
   a. Disease-Associated Maternal and/or Embryo/Fetal Risk
   b. Dose Adjustments During Pregnancy and the Postpartum Period
   c. Maternal Adverse Reactions
   d. Fetal/Neonatal Adverse Reactions
   e. Labor or Delivery
4. Data
   a. Human Data
   b. Animal Data

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.

For questions regarding this draft document contact the Division of Pediatric and Maternal Health (CDER) at 301-796-2200 or the Office of Communication, Outreach, and Development (CBER) at 240-402-8010.

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Labeling
Revision 1
Resources

• Draft Guidance for Industry: [Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials](#)
• Draft Guidance for Industry: [Postapproval Pregnancy Safety Studies](#)
• Health and Human Services (HHS) Human Subject Protection regulations, including pregnant women
• [Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)](#)
• Draft Guidance for Industry: [Pharmacokinetics in Pregnancy – Study Design, Data Analysis, and Impact on Dosing and Labeling](#)
Thank you!

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