FOOD AND DRUG ADMINISTRATION (FDA)
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Antiviral Drugs Advisory Committee
The Great Room, White Oak Conference Center, Food and Drug Administration Campus
April 28, 2011

Questions to the Advisory Committee

1. Rash associated with telaprevir use was common and sometimes severe and treatment-limiting and anemia was more frequent and more severe in patients treated with telaprevir. Please comment on the safety profile of telaprevir, focusing on the increased frequency and severity of rash and anemia when telaprevir is added to pegylated interferon and ribavirin. Do these adverse events affect your risk/benefit assessment and, if so, how?

2. Considering the overall risks and benefits, do the available data support approval of telaprevir for treatment of treatment-naive and treatment-experienced patients with chronic hepatitis C genotype 1 in combination with pegylated interferon and ribavirin?

   VOTE: Yes/No/Abstain

   a) If no, what additional studies are recommended?
   b) If yes, proceed with the remaining questions.

3. Please comment on the strength of evidence to support response-guided therapy with telaprevir in combination with pegylated interferon and ribavirin for the following patient groups?

   a) Treatment-naïve
   b) Prior relapsers

4. Please comment on the strength of evidence to support a recommendation for use in specific populations, including but not limited to Blacks/African Americans and patients with cirrhosis. What, if any, additional efficacy or safety data are needed for specific populations?

5. Are there any other post marketing studies you would like to see conducted to further define risks or optimal use of telaprevir?