Food and Drug Administration

Center for Drug Evaluation and Research (CDER)

Anti-Infective Drugs Advisory Committee in Joint Session with the Drug Safety and Risk Management Advisory Committee

December 14 & 15, 2006

The committee will discuss the overall benefit to risk considerations for the approved product KETEK (telithromycin), new drug application (NDA) 21-144, with the current indications of: acute bacterial exacerbations of chronic bronchitis, acute bacterial sinusitis, and community acquired pneumonia, manufactured by Sanofi-Aventis.

Questions to Advisory Committee

KETEK (telithromycin), new drug application (NDA) 21-144, with the current indications of: acute bacterial exacerbations of chronic bronchitis, acute bacterial sinusitis, and community acquired pneumonia, manufactured by Sanofi-Aventis.

Committee Discussion

Please discuss whether the benefits outweigh the risks for each of the approved indications for Ketek (community-acquired pneumonia, acute bacterial exacerbation of chronic bronchitis, and acute bacterial sinusitis). Please take into consideration the current safety information (specifically including hepatic, visual, loss of consciousness, and exacerbation of myasthenia gravis adverse reactions). Please also consider the information supporting efficacy for these indications as well as the recent efficacy discussions on the use of non-inferiority trial designs.

Committee Vote

Questions

1. Based on your discussions of whether or not Ketek's benefits outweigh its risks, do the available data support the continued marketing of any of the following approved indications? Please vote separately for each of the indications.

    a. Community-acquired pneumonia
    b. Acute bacterial exacerbation of chronic bronchitis
    c. Acute bacterial sinusitis

2. If continued marketing is recommended for any of the indications, please address the following:

    a. Should any of the indications for which continued marketing is recommended be modified or limited?

    b. Does the product label adequately describe the adverse reactions? Please specifically address hepatic, visual, loss of consciousness and exacerbation of myasthenia gravis adverse reactions.

c. Should any additional communication strategies or risk management programs be implemented to assure the safe use of Ketek? If yes, please describe.

d. Please recommend any additional studies to further define the benefits of Ketek for each indication.

e. Please recommend any additional studies to further define the risks of Ketek for each indication.

3. If continued marketing is not recommended for any of the indications, please address what evidence is needed to show that the benefits of Ketek outweigh the risks for those indications.