Invirase (saquinavir)

Full Safety and Drug Utilization Review Provided in Background Materials

Pediatric Advisory Committee Meeting, March 24, 2015
Invirase - Background

• Invirase is an inhibitor of human immunodeficiency virus (HIV) protease.
• It was first approved in 1995 and is indicated in combination with ritonavir and other antiretroviral agents for the treatment of HIV-1 infection in adults, >16 years of age.
• 11/30/2012  Pediatric labeling: Invirase did not receive a pediatric indication.
Invirase
Justification for Abbreviated Presentation

• 15 pediatric SAEs, including deaths (1/1/2002 to 7/31/2014). The last US FAERS case was reported in 2009.

✓ 5 deaths
  o 4 attributed to underlying disease progression (3 infections pneumococcal meningitis, urosepsis, chronic gastroenteritis and acinetobacter baumannii sepsis and 1 failed therapy)
  o 1 due to hepatic failure in a patient with advanced liver disease treated concomitantly with multiple hepatotoxic drugs

*Unlabeled events are underlined
Invirase
Justification for Abbreviated Presentation

✓ 10 Nonfatal SAEs
  o 2 GI disorders, 1 case each of Cushing’s syndrome from drug-drug interaction, pneumonia, epiglottitis, pneumocystis jiroveci pneumonia, spontaneous abortion, UTI/sepsis/convulsion, paranoid/hallucination/nightmares, treatment failure/drug resistance

• Use in pediatrics < 1% and not expected to increase
• No new safety signal identified
• Product labeling is appropriate

*Unlabeled events are underlined
Invirase (saquinavir)  
Pediatric (0-16 years) Drug Utilization  

- In Outpatient Retail Pharmacy Settings  
  - In Year 2002: approximately 300 pediatric patients  
    - <2% of total patients  
  
  - In Year 2013: <10 pediatric patients,  
    - <1% of total patients  

Source: IMS Health Total Patient Tracker®(TPT), Y2013, Extracted Oct 2014,  
Invirase (saquinavir)

FDA will continue its standard ongoing safety monitoring.

Does the Committee concur?