

## FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

*Arthritis Advisory Committee  
Marriott Inn and Conference Center  
University of Maryland University College (UMUC)  
3501 University Boulevard, East  
Hyattsville, Maryland*

### Draft Questions to the Committee

June 21, 2011

1. Discuss the efficacy data of canakinumab for gout considering the following:
  - a. The dose ranging data and whether doses lower than 150mg should be explored further.
  - b. Whether the proposed regimen (150 mg SC single-dose, with re-treatment on demand) represent acute treatment, or a more chronic treatment.
  - c. The limited information regarding repeat dosing and whether additional data on repeat dosing over time should be obtained, particularly in light of the intended population of patients, who may be at risk for more frequent flares (patients in the studies had an average of 6-7 acute flares in the previous year).
2. Discuss the overall safety profile of canakinumab for gout considering the following:
  - a. Safety signals of infections, increase in uric acid level, decline in renal function, and hypertriglyceridemia
  - b. Potential risk of using canakinumab for gout on acute recurrent basis
3. Considering the totality of data, has canakinumab at a dose of 150 mg subcutaneously demonstrated substantial evidence of efficacy for treatment of gouty arthritis attacks in patients who cannot obtain adequate response with non-steroidal anti-inflammatory drugs (NSAIDs) or colchicine? (voting question)
  - a. If not, what further efficacy data should be obtained?
4. Considering the totality of data, has canakinumab at a dose of 150 mg subcutaneously demonstrated substantial evidence of efficacy for the additional claim that canakinumab has shown to extend the time to next attack and reduce frequency of subsequent attacks? (**voting question**)
  - a. If not, what further data should be obtained?
5. Is the safety profile of canakinumab sufficient for approval of canakinumab for treatment of gouty arthritis attacks in patients who cannot obtain adequate response with NSAIDs or colchicine? (voting question)
  - a. If not, what further safety data should be obtained?
6. Do the efficacy and safety data provide substantial evidence to support approval of canakinumab at a dose of 150 mg subcutaneously for treatment of gouty arthritis attacks in patients who cannot obtain adequate response with NSAIDs or colchicine? (**voting question**)
7. Do the efficacy and safety data provide substantial evidence to support approval of canakinumab at a dose of 150 mg subcutaneously for the additional claim that canakinumab has shown to extend the time to next attack and reduce frequency of subsequent attacks? (voting questions)