Arthritis Advisory Committee
June 2, 2004
8 am – 5 pm
ACS Conference Room, 5630 Fishers Lane, Rockville, MD

Chronic Gout
(Draft) Agenda

8:00	Call to Order and Introductions	Alan Gibofsky, MD, LLB
	Conflict of Interest Statement	Kimberly Littleton Topper, M.S.
8:15	Welcome	Brian E. Harvey, MD, PhD.
	Introduction and Overview of the topic:	James P. Witter, MD, PhD
8:45	Background and Scientific Status:	Robert A. Terkeltaub, MD
9:30	Presentation, Oxyprim	Cardiome
10:30	Break	
10:45	FDA Presentation, Oxyprim	Maria Lourdes Villalba, MD
11:30	Lunch	
1:00	Open Public Hearing	
2:00	Discussion	
5:00	Adjourn	

GENERAL AREAS FOR DISCUSSION

CHRONIC GOUT AND HYPERURICEMIA TRIAL DESIGN:

The appropriate design of trials to demonstrate both efficacy and safety of new therapies for treatment of hyperuricemia associated with chronic gout is critical in order to facilitate the development of useful products. The areas for discussion at this advisory committee meeting will include the following:

1) Inclusion and exclusion criteria
    a. baseline serum uric acid level
    b. renal insufficiency
    c. subjects with tophi
2) Trial duration
3) Placebo controlled trials vs non-inferiority trials
4) Concomitant medications
5) Choice of outcome measures:
    a. serum uric acid levels
    b. number of clinical exacerbations

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Acute Gout
(Draft) Agenda

8:00	Call to Order and Introductions	Allan Gibofsky, MD, JD
	Conflict of Interest Statement	Kimberly Littleton Topper, M.S.
8:15	Welcome	Brian E. Harvey, MD, PhD.
	Introduction and Overview of the topic:	Joel Schiffenbauer, MD
8:45	Background and Scientific Status:	John J. Cush, MD
9:30	Presentation, Arcoxia for gout	Merck
10:30	Break	
10:45	Discussion	
11:30	Lunch	
1:00	Open Public Hearing	
2:00	Discussion	
5:00	Adjourn	

GENERAL AREAS FOR DISCUSSION

ACUTE GOUT TRIAL DESIGN:

Individuals with acute gout often experience significant pain. Therefore it is important to carefully assess any new therapy for both efficacy and safety. However, there have been a limited number of trials in this area. The areas for discussion during this advisory committee meeting will include the following:

1) Inclusion and exclusion criteria:
    a. polyarticular vs mono-articular gout
    b. baseline pain
2) Placebo controlled trials vs non-inferiority trials
3) Duration of trials
4) Concomitant medications
5) Choice of outcome measures
    a. methods to assess signs and symptoms