

99 AUG 20 11 37

Food and Drug Administration
Center for Drug Evaluation and Research
Ophthalmic Drugs Subcommittee of the
Dermatologic and Ophthalmic Drugs Advisory Committee
July 22, 1998
Holiday Inn, Bethesda, Maryland
NDA 20-961, Vitravene for Cytomegalovirus Retinitis

Members Present

Dermatologic & Ophthalmic Drugs
Advisory Committee

M. Roy Wilson, M.D., Chairman
Joel Mindel, M.D., Ph.D.
Johanna Seddon, M.D.
S. James Kilpatrick, Ph.D.
Sadeer Hannush, MD
Susan Cohen, B.S., Consumer
Representative

Members Present

Endocrine and Metabolic Drugs Advisory
Committee

Jose Francisco Cara, M.D.
Jaime Davidson, M.D.
Mark Molitch, M.D.
Joanna Zawadzki, M.D.

FDA Participants

Robert DeLap, M.D.
Wiley Chambers, M.D.
Debra Birnkrant, MD
Jonca Bull, MD
Lori Gorski

FDA Consultants, Guest Speakers
& Guests

Emily Y. Chew, MD
Donald S. Fong, MD, MPH
Wm Christopher Mathews, MD, MSPH
Kevin R. Frost

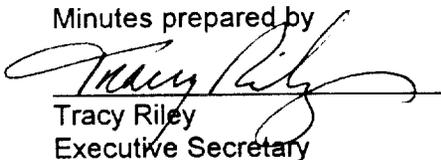
Executive Secretary

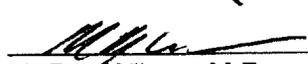
Ermona McGoodwin
Tracy Riley

These summary minutes for the July 22, 1998, Joint Meeting of the Ophthalmic Drugs Subcommittee of the Dermatologic and Ophthalmic Drugs Advisory Committee and the Endocrine and Metabolic Drugs Advisory Committee were approved on 19 August 1999.

I certify that I attended the July 22, 1998 Committee meeting and that these minutes accurately reflect what transpired.

Minutes prepared by


Tracy Riley
Executive Secretary


M. Roy Wilson, M.D.
Chairman

The July 22, 1998, meeting of the Ophthalmic Drugs Subcommittee of the Dermatologic and Ophthalmic Drugs Advisory Committee was held at the Holiday Inn, Bethesda, Maryland. Approximately 100 people attended the meeting

After the call to order, welcomes and information, M. Roy Wilson, M.D., Chairman, introduced Ms. Ermona McGoodwin, Executive Secretary, who read the Conflict of Interest Statement.

At the Open Public Hearing there were two speakers one a patient and one a patient representative, both urged approval of Vitravene. Scientific presentations of the open session began once the last open hearing participant had spoken.

Once Wiley A. Chambers, M.D. completed the introductory remarks, the scientific presentations began.

ISIS Pharmaceuticals Presentations:

Opening Remarks -	Lisa R. Grillone, Ph.D., Senior Director, Drug Development, ISIS 2922 Project Team Leader
Introduction -	Daniel L. Kisner, M.D., President/Chief Operating Officer
Clinical Presentation -	John W. (Jack) Chandler, M.D., FACS
Questions -	Daniel L. Kisner, M.D.

FDA Presentation:

Wiley A. Chambers, M.D. Deputy Director, Division of Anti-Inflammatory, Analgesic, and Ophthalmologic Drug Products

The issues at hand were the safety and efficacy of NDA 20-961, fomivirsen sodium intravitreal injection (Vitravene®, ISIS Pharmaceuticals, Inc) for the local treatment of cytomegalovirus (CMV) retinitis in patients with acquired immunodeficiency syndrome (AIDS).

Studies of Vitravene included both newly diagnosed and previously treated patients with CMV retinitis.

The primary question was, "Has sufficient evidence been submitted to support the efficacy of fomivirsen sodium intravitreal injectable in delaying progression of CMV retinitis?"

VOTE: 5 YES 2 NO

- While The Committee Voted that Vitravene be approved, members expressed concerns:
 - about the small numbers of patients in the studies (more effective treatment of HIV infection has reduced the number of patients developing CMV retinitis);
 - the relatively short time of patient exposure to drug; and
 - the role of other medications used simultaneously to treat HIV infection.
- The Committee generally agreed that additional data need to be collected.
- Of the five members recommending approval, two thought Vitravene could be used as a first line of treatment.
- Two members thought it could be a second-line treatment with a restriction to patients having failed at least one other therapy.
- One member expressed no preference for whether the product should be used for first-line or second-line use.
- Those voting against approval thought that it should be limited as much as possible. Adverse reactions were generally transient, but the Committee recommended continued monitoring, particularly in view of the small numbers of patients studied.

The Chairman thanked the participants and adjourned the meeting at 2:55 p.m.

Verbatim transcripts of this meeting are available on the FDA Website, www.FDA.GOV.