

Gastrointestinal Drugs Advisory Committee

Food and Drug Administration
Center for Drug Evaluation and Research
Marriott Washingtonian Center, 9751 Washington Boulevard, Gaithersburg, MD

New drug application (NDA) 21-525, Photofrin® (porfirin sodium), Axcan Scandipharm Inc.

“Photodynamic therapy with Photofrin® is indicated for the ablation of high-grade dysplasia in Barrett’s esophagus among patients who refuse esophagectomy and who are in overall good health.”

Agenda for June 26, 2003

- 8:30 Call to Order, Introductions:** M. Michael Wolfe, M.D., Acting Chair
Meeting Statement: Thomas H. Perez, M.P.H., Executive Secretary
- 8:45 Opening Comments:** Robert Justice, M.D., Director,
Division of Gastrointestinal and Coagulation Drug Products
- 8:50 Axcan Scandipharm Inc., Presentation**
Introduction
François Martin, M.D., Senior Vice President, Scientific Affairs, Axcan Scandipharm, Inc.
Management of High-Grade Dysplasia in Barrett’s Esophagus
Kenneth K. Wang, M.D., Associate Professor of Medicine, Mayo Clinic
**Efficacy & Safety of Photofrin Photodynamic Therapy
in the ablation of High-Grade Dysplasia in Barrett’s Esophagus**
Bergein F. Overholt, M.D., Medical Director, Thompson Cancer Survival Laser Center Center, Knoxville, TN
Histopathology of High-Grade Dysplasia in Barrett’s Esophagus
Mary P. Bronner, M.D., Director, GI and Hepatic Pathology Program, The Cleveland Clinic Foundation
Conclusion
François Martin, M.D., Senior Vice President, Scientific Affairs
- 10:35 Break**
- 10:50 Questions on Presentations**
- 11:20 FDA Presentation**
Medical Officer’s Presentation
Edvardas Kaminskas, M.D., Division of Gastrointestinal and Coagulation Drug Products
- 11:50 Questions on Presentation**
- 12:20 Lunch**
- 1:20 Open Public Hearing**
- 2:20 Charge to the Committee**
Robert Justice, M.D., Director, Division of Gastrointestinal and Coagulation Drug Products
- 2:25 Committee Discussion**
- 3:30 Break**
- 3:45 Committee Discussion – continued**
- 5:00 Adjourn**