

## **Anti-Infective Drugs Advisory Committee**

Food and Drug Administration  
Center for Drug Evaluation and Research

Hilton Gaithersburg, 620 Perry Parkway, Gaithersburg, MD

Biologic License Application (BLA) 125029  
Xigris™ (drotrecogin alfa (activated)), Eli Lilly and Company

### **Agenda - October 16, 2001**

- 8:30 Call to Order, Introductions:** Barth Reller, M.D., Chair
- Meeting Statement:** Thomas H. Perez, M.P.H., Executive Secretary
- Opening Comments:** Gibbes Johnson, Ph.D., Chair, FDA Review Team
- 9:00 Eli Lilly and Company Presentation:**
- Introduction –**  
Holger Schilske, M.D., Ph.D. – Executive Director, Eli Lilly and Company
  - Pathophysiology of Severe Sepsis – Rationale for Drotrecogin Alfa (activated)**  
Steven Opal, MD – Chief Infectious Disease Division Brown University School of Medicine
  - Efficacy and Safety of Drotrecogin Alfa (activated) in the Treatment of Severe Sepsis**  
William Macias, M.D., Ph.D. – Medical Director, Eli Lilly and Company
  - Benefit-Risk Assessment of Drotrecogin Alfa (activated) in the Treatment of Severe Sepsis**  
Jeffrey Helterbrand, Ph.D. - Senior Statistical Scientist, Eli Lilly and Company
  - Clinical Experience in Pediatric Patients with Severe Sepsis and Overall Conclusions**  
William Macias, M.D., Ph.D. – Medical Director, Eli Lilly and Company
- 10:30 Break**
- 10:45 FDA Presentation:**
- Summary of Efficacy**  
Linda Forsyth, M.D., Medical Officer, Center for Biologics Evaluation and Research, FDA
  - Pediatric Data and Summary of Adult Safety**  
Robert Lindblad, M.D., Medical Officer, CBER, FDA
- 12:30 Lunch**
- 1:30 Open Public Hearing**
- 2:30 Charge to the Committee, Introduction to Questions:**
- 3:30 Break**
- 3:45 Discussion and Questions**
- 5:00 Adjourn**

## **Consultants and Guests**

Thomas Fleming, Ph. D., Cardiorenal Drugs Advisory Committee Member  
Robert Munford, M.D., Department of Internal Medicine, Univ. of Texas Southwestern Medical Center  
H. Shaw Warren, M.D., Infectious Disease Unit, Massachusetts General Hospital  
Anthony Suffredini M.D., Critical Care Medicine Department, National Institutes of Health  
Leo C. Rotello, M.D., Medical Director, Surgical Intensive Care Unit, Surburban Hospital  
Craig M. Lilly, M.D., Assistant Professor of Medicine, Brigham and Women's Hospital  
Joseph A. Carcillo, M.D., Intensive Care Services Department, Children's Hospital of Pittsburgh  
Peter Eichacker, M.D., Head, Critical Care Section, Warren G. Magnuson Clinical Center  
W. Michael O'Fallon, Ph.D., Chair, Department of Health Sciences Research, Mayo Clinic

## **Open Public Hearing**

William Lyons, M.D. (*Representing Self*)  
Edward Wiginton, Meningitis Foundation of America  
Alvin Lever, M.A., American College of Chest Physicians  
Alvin Thomas Jr., M.D., American College of Chest Physicians  
Thomas Smirniotopoulos M.D., (*Representing Self*)