

Factive[®] (gemifloxacin)
Anti-Infective Drugs Advisory Committee

September 12, 2006

Gemifloxacin

An Important Therapeutic Option in ABS

- Excellent PK/PD parameters
- High response rate in clinical trials
- Effective against resistant organisms
- Effective in short courses of therapy

Gemifloxacin

Consistent Safety Profile

We will present:

- General safety and rash data
- AE/SAE comparisons with marketed ABS antibiotics
- Favorable risk/benefit

Gemifloxacin Regulatory History

- 2003 – Advisory Committee vote
 - 18 - 0 CAP (1 abstention)
 - 15 - 3 ABECB (1 abstention)
- 2003 – FDA approval AEBCB & CAP
- 2005 – sNDAs – 5-day CAP& ABS
 - Larger safety database than 2003

Gemifloxacin Proven Efficacious in 5-Day ABS Treatment

- State-of-the-art trials conducted 1998-2001
 - Met FDA trial design standards
 - Met all primary/secondary efficacy endpoints
- Four recent ABS approvals -- same design
- FDA communicated drug efficacious in ABS

Gemifloxacin Clinical Development Program

2002 NDA

- Original Clinical Program (n=6,775)
 - 7-day ABS clinical trials (009,010)
 - 5-day ABS clinical trials (186,206)

2005 sNDA

- 5-day CAP (634-001)
- 5-day open-label ABS (333)
- Open-label CAP (287)

Ongoing (scheduled interim reports)

- Phase IV FORCE Study (n=1,821)
- Prescribing Use Study (n=4,910)
- U.S. post-marketing experience (n~760,000)

(n=6,775)

(n=1,344)

N=8,119

“Acute Bacterial Sinusitis is a Serious Health Issue”

- Respiratory infections #1 in doctor visits
- ABS most common adult RTI
- 800 million cases of rhinosinusitis/year
- 5-20 million ABS cases/year
- Need to limit antibiotic resistance in ABS

Agenda

- **Introduction**

Gary Patou, MD

Director

Oscient Pharmaceuticals

- **Antimicrobial Resistance**

Donald E. Low, MD

Professor

Microbiology and Medicine

University of Toronto

- **Efficacy**

B.J. Ferguson, MD

Director

Division of Sino Nasal Disorders and Allergy

Dept. of Otolaryngology Head and Neck Surgery

University of Pittsburgh School of Medicine

Agenda (continued)

- **Cutaneous**

Neil Shear, MD

*Professor and Chief of Dermatology
Director, Drug Safety Research
University of Toronto*

- **Safety**

Paul Waymack, MD, ScD

*President
Waymack Associates*

- **Benefit/Risk**

Gary Patou, MD

*Director
Oscient Pharmaceuticals*

Additional Experts

- **Wayne Dankner, MD**

*Sr. Medical Director, Parexel
Associate Professor
Duke University Medical School*

- **Paul Watkins, MD**

*Professor of Medicine
Professor of Pharmacotherapy
Director, General Clinical Research
University of North Carolina*

- **Judith Jones, MD, PhD**

*Adjunct Professor
Georgetown University School of Medicine
Adjunct Professor
University of Michigan School of Public Health*

- **M. Jean Barbey, MD**

*Medical Director,
Core Cardiology Laboratory
Medifacts International*

- **Jack Gwaltney, Jr, MD**

*Chief
Division of Epidemiology and Virology
University of Virginia
Director
Center for Prevention Disease and Injury
Professor Emeritus*