

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK)

Novel Therapies to Enhance Survival Inflammation in ESRD

Bethesda Marriott Hotel, Bethesda, Maryland

April 21 - 22, 2010

DAY 1: Wednesday, April 21, 2010

- 7:00 – 7:50 a.m.** **Registration**
- 7:50 – 8:15 a.m.** **Opening Remarks and Objectives**
Dr. Star and Dr. Kimmel
- 8:15 – 9:00 a.m.** **Overview/Introduction** (*30 minutes, followed by 15 minutes of discussion*)
Moderator: Dr. Korzenik
- *Cytokine Milieu and Outcomes in ESRD Hemodialysis Patients – Dr. Stenvinkel*
- 9:00 – 10:00 a.m.** **Progress in Cytokine Therapeutics** (*20 minutes, followed by 10 minutes of discussion*)
Moderator: Dr. Carter
- *Lessons for Nephrologists From Lupus – Dr. Aringer*
 - *Lessons for Nephrologists From Treatment of Inflammatory Bowel Disease – Dr. Korzenick*
- 10:00 – 10:30 a.m.** **BREAK**
- 10:30 – 12:00 p.m.** **Progress in Cytokine Therapeutics** (*20 minutes, followed by 10 minutes of discussion*)
Moderator: Dr. Lipsky
- *Lessons for Nephrologists From Treatment of Rheumatoid Arthritis – Challenges, Successes, and Combination Therapies – Dr. Weinblatt*
 - *Lessons for Nephrologists From Treatment of Psoriasis – Dr. Gottlieb*
 - *Non-Cytokine Anti-Inflammatory Therapeutics for ESRD Dialysis Patients – Targets and Armamentarium – Dr. Ikizler*
- 12:00 – 1:00 p.m.** **LUNCH**
- 1:00 – 2:30 p.m.** **Plenary Session** (*30 minutes, followed by 15 minutes of discussion*)
Moderator: Dr. Chertow
- *Anti-Cytokine Therapies — What Works and What Doesn't – and Why*
Dr. Oppenheim

- *Lessons for Nephrologists From Treatment of ESRD Patients – Challenges, Successes, Adverse Events, and Clinical Trials Tips* – **Dr. Kaysen**

2:30 – 3:30 p.m. **Progress and Perils in Cytokine Therapeutics** (20 minutes, followed by 10 minutes of discussion)

Moderator: Dr. Gottlieb

- *Lessons for Nephrologists from Treatment of a Genetic Disorder – Challenge and Success* – **Dr. Goldbach-Mansky**
- *FDA Viewpoints – Adverse Effects of Anti-Cytokine Therapies – Cancer, Infection, and Others* – **Dr. Siegel**

3:30 – 4:00 p.m. **BREAK**

4:00 – 4:30 p.m. **Challenges in Clinical Trials in the ESRD Patient** (20 minutes, followed by 10 minutes of discussion)

Moderator: Dr. Weinblatt

- *Pilot and Feasibility Issues, Power Analyses, Adverse Effects, Biomarkers, Endpoints* – **Dr. Chertow**

4:30 – 6:30 p.m. **Breakout Sessions – Charge**

Dr. Kimmel

Breakout Session Leaders:

Dr. Kaskel, Dr. Himmelfarb, Dr. Liu, Dr. Cheung, TBD

Group Discussion:

- A. Adverse Events
- B. Pilot and Feasibility Issues
- C. Combination Therapies and Biologic Issues
- D. Patient Selection — Inclusion/Exclusion Criteria
- E. Biomarkers/Surrogate Markers

6:30 p.m. **ADJOURN**

DAY 2: Thursday, April 22, 2010

7:00 – 8:00 p.m. **Registration**

8:00 – 8:30 a.m. **Plenary Session** (20 minutes, followed by 10 minutes of discussion)

Moderator: Dr. Stenvinkel

- *Lessons for Nephrologists From Treatment of Diabetes Mellitus* – **Dr. Donath**

- 8:30 – 9:30 a.m.** **Presentations** (*20 minutes, followed by 10 minutes of discussion*)
- *Public – Private Partnerships/Collaborative Opportunities/An NIH View – Dr. Mayrand-Chung*
 - *Intellectual Property – An NIDDK View – Ms. Lake*
- 9:30 – 11:30 a.m.** **Industry Round Table**
- **Abbott – Dr. Andress**
 - **Amgen – Dr. Pollock**
 - **Celgene – Dr. Stevens**
 - **J and J / Centocor – Dr. Chevrier**
 - **Novartis – Dr. Lorber**
 - **Regeneron – Dr. Mellis**
 - **Roche / Genetech – Dr. Lee**
 - **UCB – Dr. Chartash**
- 11:30 – 12:00 p.m.** ***BREAK***
- 12:00 – 2:00 p.m.** ***WORKING LUNCH***
- 2:00 – 3:00 p.m.** **Reports from the Breakout Sessions**
- 3:00 – 4:00 p.m.** **Open discussion**
- 4:00 p.m.** ***ADJOURN***