

**Food and Drug Administration
Center for Biologics Evaluation and Research
BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE
AGENDA
Meeting #31, Holiday Inn, Gaithersburg, MD
October 24-26, 2001**

Thursday, October 25

- 8:00 a.m. Opening Remarks
 Dr. Daniel Salomon, Chair
- 8:15 Conflict of Interest Statement
 Gail Dapolito, Executive Secretary
- 8:20 Introduction of Committee

OPEN COMMITTEE DISCUSSION

Topic 1 – Lentivirus Vectors in Gene Transfer Clinical Trials

- 8:30 Lentiviral Vectors
 Dr. Inder Verma,
 Salk Institute for Biological Studies
- 9:00 Q&A
- 9:15 Lentiviral Vectors: Safety Issues
 Dr. Daniel Takefman
 Office of Therapeutics Research and Review, CBER
- 9:45 Q&A
- 10:00 Break
- 10:15 Lentiviral Gene Therapy
 Dr. Dale Ando
 Cell Genesys, Inc.
- LentiKat™ Vectors Overview
 Dr. Veres Gabor
 Cell Genesys, Inc.
- 11:00 Q&A

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Thursday, October 25 (cont'd)

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| 11:15 | Lentivirally Delivered GDNF for Parkinson's Disease
Dr. Jeffrey Kordower
Rush Presbyterian Medical Center |
| 12:00 | Q&A |
| 12:15 p.m. | Lunch |
| 1:15 | Lentiviral Vectors for the Treatment of Cancer, Neurodegenerative
Diseases and AIDS
Dr. Susan Kingsman
Oxford BioMedica (UK) Ltd. |
| 2:00 | Q&A |
| 2:15 p.m. | Predicting Lentiviral Vector Safety In Vivo
Dr. John Kappes
University of Alabama at Birmingham |
| 2:45 | Q&A |
| 3:00 | Open Public Hearing |
| 3:15 | Break |
| 3:30 | Committee Discussion of Questions |
| 6:00 | Adjourn |

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Friday, October 26

8:00 a.m. Opening Remarks
 Dr. Daniel Salomon, Chair

OPEN COMMITTEE DISCUSSION

Topic 2 – Lentivirus Vector Gene Transfer Product for Treatment of People with HIV

8:15 Autologous T Cells Transduced with VRX496 - HIV-1 Based Lentiviral
 Vector Treatment of Patient-Subjects Infected with HIV-1
 Dr. Boro Dropulic
 VIRxSYS Corp.

9:45 Q&A

10:00 Break

10:15 **Open Public Hearing**

10:30 **Committee Discussion of Questions**

12:00 noon Lunch

12:30 p.m. **Committee Discussion (cont'd)**

2:00 Adjourn