# AGENDA

**July 24, 2007**

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| 8:00 a.m. | Call to Order<br>Introduction of Committee | **Maha Hussain, M.D.**<br>Chair, ODAC |
| | Conflict of Interest Statement | **Johanna Clifford, M.Sc., RN**<br>Designated Federal Officer (DFO), ODAC |
| 8:15 a.m. | Opening Remarks | **Richard Pazdur, M.D., Director**<br>Office of Oncology Drug Products (OODP), FDA |

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*The committee will discuss new drug application (NDA) 022-042, EVISTA (raloxifene hydrochloride) Tablets, Eli Lilly and Company, proposed indications for the reduction in risk of invasive breast cancer in postmenopausal women with osteoporosis, and for the reduction in risk of invasive breast cancer in postmenopausal women at high risk of breast cancer*

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| 8:25 a.m. | Designing and Analyzing Trials with Active Control Arms | **David Harrington, Ph.D.**<br>Dana-Farber Cancer Institute |
| 8:40 a.m. | **Sponsor Presentation**<br>Introduction | **Eli Lilly & Company**<br>**Gwen Krivi, Ph.D.** |
| | Benefits and Risks of Evista - MORE/CORE/RUTH | **Steven R. Cummings, M.D.**<br>Director, San Francisco Coordinating Center<br>Professor of Medicine and Epidemiology (emeritus)<br>CPMC Research Institute and UC, San Francisco |
| | Benefits and Risks of Evista - STAR | **Larry Wickerman, M.D.**<br>National Surgical Adjuvant Breast and Bowel Project |
| | Benefits and Risks of Evista - Conclusions | **George Sledge, M.D.**<br>Indiana University School of Medicine |
| 9:25 a.m. | **FDA Presentation**<br>Medical Review | **NDA 22-042**<br>**Patricia Cortazar, M.D.**<br>Clinical Reviewer, DDOP, OODP, CDER<br>&<br>**Bhupinder Mann, MBBS**<br>Clinical Reviewer, DDOP, OODP, CDER |
| 10:00 a.m. | Questions from the Committee | |
| 10:30 p.m. | Break | |
| 10:45 p.m. | Open Public Hearing | |
| 11:15 a.m. | Questions to the ODAC and ODAC Discussion | |
| 12:15 p.m. | *Lunch* | |

# AGENDA



*The committee will discuss NDA 021-801, proposed trade name ORPLATNA (satraplatin capsules), GPC Biotech Inc., proposed indication for the treatment of patients with androgen independent (hormone refractory) prostate cancer (HRPC) that has failed prior chemotherapy.*

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| 1:00 p.m. | Call to Order<br>Introduction of Committee | **S.Gail Eckhardt, M.D.**<br>Acting Chair, ODAC |
| | Conflict of Interest Statement | **Johanna Clifford, M.Sc., RN**<br>Designated Federal Officer (DFO), ODAC |
| 1:15 p.m. | Opening Remarks | **Richard Pazdur, M.D., Director**<br>Office of Oncology Drug Products (OODP), FDA |
| 1:25 | **Sponsor Presentation**<br>Introduction to NDA 21-801:<br>Satraplatin Capsules | **GPC BioPharma, Incorporated**<br>**Martine George, M.D.**<br>Senior Vice President, Clinical Development |
| | Second Line Chemotherapy for<br>Hormone Refractory Prostate Cancer | **Nicholas J. Vogelzang, M.D.**<br>Director, Nevada Cancer Institute |
| | Efficacy and Safety of Satraplatin:<br>SPARC Trial<br>Summary and Conclusions | **Marcel Rozencweig, M.D.**<br>Chief Medical Officer |
| 2:10 p.m. | **FDA Presentation**<br>Clinical Review | **NDA 21-801**<br>**Martin Cohen, M.D.**<br>Clinical Reviewer, DDOP, OODP, FDA |
| | Methods Used to Assess & Report<br>Pain-Related Endpoints | **Ethan Basch M.D., MSc**<br>Study Endpoints and Label Development Team<br>Office of New Drugs, CDER, FDA |
| 2:45 p.m. | Open Public Hearing | |
| 3:15 p.m. | Break | |
| 3:30 p.m. | Questions from the Committee | |
| 4:00 a.m. | Questions to the ODAC and ODAC Discussion | |
| 5:00 p.m. | *Adjourn* | |