

**Agenda for Fall 2013 NCI CTEP Early Drug Development Meeting
September 9–10, 2013
Natcher Auditorium**

Monday, September 9, 2013

8:30 a.m. Welcome/ Introduction
John Wright, IDB, CTEP, NCI

CTEP Early Phase Trials Status Update Session

Phase I Clinical Trial Status Update Session

Moderators: Austin Doyle, James Zwiebel, Nita Seibel, IDB/CIB, CTEP, NCI

8:35 a.m.–8:50 a.m. COG Phase 1 Dose Escalation Study of Reolysin, a Replication Competent Reovirus, in Pediatric Patients With Relapsed or Refractory Solid Tumors.
E. Anders Kolb, Nemours/duPont Pediatrics

8:50 a.m.–9:05 a.m. Phase I Study of the MEK1/2 Inhibitor Selumetinib (AZD6244 Hydrogen Sulfate) in Children and Young Adults with Neurofibromatosis Type 1 (NF1) and Inoperable Plexiform Neurofibromas.
Brigitte Widemann, Pediatric Oncology Branch–CCR

9:05 a.m.–9:20 a.m. PBTC Phase 1 and Pharmacokinetic Study of AZD6244 for Recurrent or Refractory Pediatric Low Grade Glioma.
Anu Banerjee, U California San Francisco

9:20 a.m.–9:35 a.m. Phase I/II Study of E7389 Halichondrin B Analog in Metastatic Urothelial Tract Cancer and Renal Insufficiency.
David I. Quinn, USC

9:35 a.m.–9:50 a.m. GOG Phase I Pharmacokinetic Study of Intraperitoneal Bortezomib (PS-341) and Carboplatin in Patients with Persistent or Recurrent Ovarian, Fallopian Tube, or Primary Peritoneal Cancer.
Danielle Jandial, UCLA

9:50 a.m.–10:10 a.m. Panel discussion

10:10 a.m.–10:30 a.m. BREAK

Phase II Clinical Update Session

Moderators: Alice Chen, Helen Chen, Richard Piekarz, IDB, CTEP, NCI

10:30 a.m.–10:45 a.m. Pilot Trial of Molecular Profiling and Targeted Therapy for Advanced Non-Small Cell Lung Cancer, Small Cell Lung Cancer, and Thymic Malignancies.
Giuseppe Giaccone, Georgetown University

10:45 a.m.–11:00 a.m. ECOG Randomized Phase II Study of Cisplatin and Etoposide in Combination With Either Hedgehog Inhibitor GDC-0449 or IGF-1R MoAb IMC-A12 for Patients With Extensive Stage Small Cell Lung Cancer.
Chandra Belani, Penn State University

11:00 a.m.–11:15 a.m. Phase II Randomized Trial of the Combination of Cetuximab and Sorafenib or Single Agent Cetuximab in Patients With Refractory, Recurrent and/or Metastatic Squamous Cell Carcinoma of the Head and Neck.
Christine Chung, Johns Hopkins University

- 11:15 a.m.–11:30 a.m. SWOG Phase II Trial of the Aurora Kinase A Inhibitor MLN8237 in Relapsed or Refractory Peripheral T-Cell Non-Hodgkins Lymphoma.
Paul Barr, University of Rochester
- 11:30 a.m.–11:45 p.m. Phase II Trial of Single Agent ABT-888 With Post-Progression Therapy of ABT-888 in Combination With Carboplatin in Patients With Stage IV BRCA-Associated Breast Cancer.
George Somlo, City of Hope
- 11:45 a.m.–12:05 p.m. Panel Discussion
- 12: 05 p.m.–1:15 p.m. LUNCH

Educational Session on Novel Antibody-based Therapeutics:

Moderators: Helen Chen, Elad Sharon, IDB, CTEP, NCI

- 1:15 p.m.–1:20 p.m. Introduction
Helen Chen and Elad Sharon, IDB, CTEP, NCI
- 1:20 p.m.–1:50 p.m. Principles of Antibody Drug Conjugate Design and Development: Brentuximab Vedotin and Beyond.
Jonathan Drachman, Seattle Genetics
- 1:50 p.m.–2:20 p.m. Antibody Drug Conjugates in Clinical Trials.
Howard Burris, Sarah Cannon Research Institute
- 2:20 p.m.–2:35 p.m. GPNMB, a Novel Target for Antibody Drug Conjugate Therapy.
Tom Davis, CellDex
- 2:35 p.m.–3:00 p.m. Immunotoxin Therapies and Emerging Concepts.
Ira Pastan, CCR, NCI
- 3:00 p.m.–3:30 p.m. Bispecific T-cell-engager (BiTE) Antibodies.
Stanley Frankel, Amgen
- 3:30 p.m.–3:45 p.m. Panel Discussion
- 3:45 p.m.–4:00 p.m. BREAK

Educational Session on Advances in Clinical Trials:

Moderators: Alice Chen, IDB, CTEP, NCI

- 4:00 p.m.–4:30 p.m. Towards Improved Precision in Evaluating Symptomatic Treatment Toxicity: NCI's Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events.
Sandra A. Mitchell, NCI, Ethan Basch, Memorial Sloan Kettering Cancer Center

Seventh Annual Michaele C. Christian Oncology Development Award & Lecture

- 4:30 p.m.–4:40 p.m. Introduction
Jeff Abrams, CTEP, NCI
- 4:40 p.m.–4:45 p.m. Presentation of Award
John Wright, IDB, CTEP, NCI
- 4:45 p.m.–5:00 p.m. Awardee Lecture

Tuesday, September 10, 2013

7:25 a.m.–8:25 a.m. UO1 and NO1 Investigators Meeting (closed)
Bldg. 45, Natcher, Room D

**Education Session: Therapeutic Strategies Targeting
Epigenetic Mechanisms Contributing to Cancer**

Moderators: Richard Piekarz, Naoko Takebe, IDB, CTEP, NCI

8:30 a.m.–9:00 a.m. MMSET Mutations in Cancer.

Jonathan Licht, Northwestern University

9:00 a.m.–9:30 a.m. Targeting Histone Methylation in Leukemia.

Scott Armstrong, Memorial Sloan Kettering Cancer Center

9:30 a.m.–10:00 a.m. New Applications for DNA Methyltransferase Inhibitors.

Stephen Baylin, Johns Hopkins University

10:00 a.m.–10:10 a.m. Discussion

10:10 a.m.–10:25 a.m. BREAK

10:25 a.m.–10:45 a.m. Therapeutic Agents for New Epigenetic Targets.

Peter Tummino, Glaxo Smith Kline

10:45 a.m.–11:05 a.m. Development of Histone Methyltransferase Inhibitors for the Treatment of Genetically Defined Cancers.

Heike Keilhack, Epizyme Inc

11:05 a.m.–11:25 a.m. Molecular Biology of Mutations in IDH.

Craig Thompson, Memorial Sloan Kettering Cancer Center

11:25 p.m.–11:45 p.m. Discussion

11:45 p.m. ADJOURN