Public Summary
Investigational Drug Steering Committee (IDSC)
Monday, July 19th, 2010, 9:30am – 4:00pm CDT

1) Call to Order/Introductions, and Review of Minutes

a) **Motion 1**: The IDSC teleconference minutes from June 9, 2010 were approved.
b) Amy Gravell or LeeAnn Jensen will send ballots to all U01 holders for the U01 IDSC co-chair position. Dr. Michael Grever's term ends on December 31, 2010.
c) **Coordinating Center for Clinical Trials (CCCT) update**: The IDSC Winter 2011 meeting will be scheduled for Friday, January 14th, 2011 in Chicago, IL (O'Hare Hyatt).
d) Special thanks to George Wilding (Angiogenesis TF) and Razelle Kurzrock (Signal Transduction TF) for 3+ years of Task Force co-chair service.
e) **Cancer Therapy Evaluation Program (CTEP) update**: James Zwiebel discussed the Lustgarten Foundation for pancreatic cancer (which is interested in supporting correlative studies in CTEP-sponsored trials).

2) Open Discussion Regarding New Agents/Targets to Bring into the CTEP Portfolio

a) **Focus on Autophagy** – Robert DiPaola provided an update from the CTEP Early Drug Development (EDD) session on Autophagy, regarding current clinical trial status, biomarker pursuit and Clinical Cancer Research (CCR) article beginning developed by CTEP EDD speakers from March 23, 2010.
b) Joseph Sparano (IDSC Breast Cancer Steering Committee (BCSC) liaison) updated IDSC members on the NCI BCSC meeting focusing on prioritization of novel breast cancer agents. It was discussed that IDSC liaisons to the CCCT disease-specific steering committees (DSSC) should meet by telephone to discuss quarterly updates to their respective committees.

3) Cardiovascular Toxicities Panel (CTP) – Recommendations for Project # 2 *(Steingart)*

a) Richard Steingart presented the CTP's draft consensus report on the assessment and management of cardiac toxicity in patients receiving VEGF inhibitors. The report summarizes the action of VEGF inhibitors, discusses potential causes of cardiotoxicity and provides principles for future investigation and to improve the safety of administering these drugs. Although pre-existing hypertension and cardiovascular disease are common in cancer patients, active monitoring and patient management in collaboration with specialists, especially during the first cycle of treatment, may allow safe use of this class of drugs. The IDSC asked Dr. Steingart to distill the report into specific recommendations, especially as related to investigational agents, and asked interested IDSC members to provide comments. (The CTP is a subcommittee of the IDSC's Angiogenesis Task Force. A report on hypertension and VEGF inhibitors was recently published: Maitland ML, et al, J Natl Cancer Inst. 2010 May 5;102(9):596-604.)

b) The IDSC suggested that the CTP consider a project on QTc prolongation (Drs. Joanna Brell and Lillian Siu are interested in assisting with this project).

4) CTEP Drug Development Plan – AMG386 (Ang 1/2)

a) CTEP is planning to add the Ang 1 / 2 inhibitor, AMG386 to its portfolio (*further information is confidential).*
b) Angiogenesis TF recommendations on CTEP's clinical development plan were presented to the IDSC and approved with modifications.
c) The mass solicitation will be sent to IDSC members when available.

5) Clinical Trial Design (CTD)Task Force

a) Mark Ratain presented a comparative analysis of the CTD Phase 2 clinical trial design recommendations (approved on July 24, 2009) and approved LOIs received by CTEP from July 2009-April 2010 to determine concordance.
b) The IDSC recommended that CTEP provide the IDSC CTD Phase 2 recommendations to investigators prior to LOI submission.
c) The IDSC recommended that concordance of approved LOIs with the IDSC CTD Phase 2 recommendations be prospectively tracked.

6) Immunotherapy Task Force

a) Mario Sznol (Task Force chair) presented the adoptive immunotherapy white paper developed on behalf of the IDSC's Immunotherapy TF and targeted at CTEP. The whitepaper notes that adoptive transfer of effector cells is a clinically promising but complex procedure that needs an adequately-powered randomized, controlled trial. A multi-institution phase 2 trial with a central facility for cell growth was recommended.
b) The IDSC endorsed the adoptive immunotherapy white paper. The paper may be shared with members of the scientific community.
c) The IDSC recommended that to obtain NCI resources to support adoptive immunotherapy, the investigators who wrote the white paper submit a proposal to the NCI Experimental Therapeutics (NExT) program. More information about the NExT program is available at http://next.cancer.gov/

7) CTEP Drug Development Plan – ARQ-197 (c-Met)

a) CTEP is considering a c-Met inhibitor (ARQ-197) for its portfolio (*further information is confidential).*
b) Signal Transduction TF recommendations were presented to the IDSC.
c) The mass solicitation will be sent to IDSC members when available.

8) Pharmacology Task Force (Jerry Collins/Edward Newman)

a) James Zwiebel (NCI/CTEP/IDB Chief) has requested that the Pharmacology Task Force review a new methodology for creatinine measurements recently adopted by many clinical laboratories and consider the impact on carboplatin dose determinations. Drs. Ned Newman, Merrill Egorin, and Jerry Collins (Task Force leadership) have agreed to do so.
b) The Pharmacology Task Force will hold a teleconference on Thursday, July 22nd (2010) and an in-person evening meeting on Monday, September 27th (2010) to discuss this issue.

9) **Future Plans/Calls/Meetings:**
   a) **Next call: TBD**
   b) **Fall 2010 CTEP EDD/IDSC Meeting**: Monday-Wednesday, September 27-29th, 2010 (Bethesda, MD)
   c) **IDSC Winter 2011 Meeting**: Friday, January 14th, 2011 (Chicago, IL)
   d) **Spring 2011 CTEP EDD/IDSC Meeting**: Monday-Wednesday, March 14-16th, 2011 (Bethesda, MD)