Public Summary
Investigational Drug Steering Committee (IDSC)
Tuesday, March 13th (2012)

1) **Call to Order, Introductions and Review of Minutes**
   a) **Motion 1**: The IDSC meeting minutes from the January 13th meeting were approved.
   b) **Announcements***:*
      i) **PI3K/Akt/mTOR (PAM) TF:** The hyperglycemia and hyperlipidemia PAM TF manuscript has been accepted by JCO (congratulations to Drs. Lillian Siu and Afshin Dowlati).
      ii) **New or Rotating IDSC members:**
         (1) John Carpten (TGEN) – Genomics Expert
         (2) Charles Shapiro (OSU) – IDSC SxQOL Liaison
         (3) Brenda Weigel will replace Susan Blaney as the COG Phase 1 representative
   c) **Biomarker TF (Tissue-based Biomarker Assays Subcommittee) (Jessup)***:* Dr. Kim Jessup reviewed the mutation assay template with IDSC members. This template and the IHC and DNA-based ISH templates developed by this group are listed on the NCI Cancer Diagnosis Program (CDP) and Cancer Therapy Evaluation Program (CTEP) websites (see links below).
      i) IDSC members would like to see these templates piloted by CTEP/DCTD. They are for informational purposes only at this juncture.
      ii) **CDP website**: http://www.cancerdiagnosis.nci.nih.gov/diagnostics/templates.htm
      iii) **CTEP website (look at the Ancillary/Correlatives section)**: http://ctep.cancer.gov/protocolDevelopment/default.htm#lois_concepts

2) **CTEP Drug Development Plan – AZD1480 (JAK2 inhibitor;** *Richard Piekarz)*
   a) CTEP is planning to add the JAK2 inhibitor; AZD1480 to its portfolio (*further information is confidential*).
   b) The IDSC endorsed the AZD1480 CTEP drug development plan with minor modifications.
   c) A presolicitation or mass solicitation will be developed and distributed.

3) **Clinical Trial Design Phase 1 Combination Recommendations (Ratain):**
   a) A small group, led by Dr. Mark Ratain, has drafted a set of Recommendations for the Design of Agent Combination Studies.
   b) The IDSC endorsed the recommendations and approved this project to move forward as a manuscript.

4) **Redesign of the U01 Program – Part 2 (Ivy)** – *further information on this topic is confidential.*

5) **Dr. Elad Sharon (IDB drug monitor) presented the CTEP Drug Development Plan for Moxetumomab pasudotox (HA22) to the IDSC as an FYI**.
   a) A phase 3 trial will be placed with the NCI-CCR with additional sites.
   b) No mass solicitation will be sent for this agent.

6) Future Plans/Calls/Meetings:

a) Next call: TBD

b) **Summer 2012 IDSC Meeting:** Friday, July 13th in Chicago, IL

c) **Fall 2012 CTEP EDD/IDSC Meeting:** Monday-Wednesday, October 15-17th, 2012 (Bethesda, MD)

d) **Spring 2013 CTEP EDD/IDSC Meeting:** Monday-Wednesday, March 18-19, 2013 (Bethesda, MD)