

**Public Summary
Investigational Drug Steering Committee (IDSC)
Friday, July 13th (2012)**

- 1) **Call to Order, Introductions and Review of Minutes**
 - a) **Motion 1:** The IDSC meeting minutes from the March 13th meeting were approved.
 - b) **CCCT Update (Reeves):** Approximately 1-2 months prior to the IDSC Task Force (TF) presentation, 1-2 disease-specific representatives from relevant disease Steering Committees (SCs) will be asked to attend the IDSC TF Clinical Development Plan webinar review and report back to their groups.
 - c) **CTEP Update:** CTEP is prepared to accept proposals for preclinical studies and unsolicited LOIs for ABT-263.

- 2) **CTEP Drug Development Plan – MLN0128 (TORC1/TORC2 inhibitor; Austin Doyle)**
 - a) CTEP is planning to add the TORC1/TORC2 inhibitor; MLN0128 to its portfolio (*further information is confidential*).
 - b) After a lengthy discussion, the IDSC endorsed the limited MLN0128 CTEP drug development plan (voting was 20 to 11).
 - c) Dr. Austin Doyle (IDB drug monitor) has gone to the company with other clinical trial proposals discussed on the PI3K/Akt/mTOR (PAM) and Signal Transduction TF calls. They have not gotten back to him on these points as of yet.
 - i) Pharmacodynamic biomarker study with MLN0128.
 - ii) Pharmacokinetic study (dosing question) with MLN0128.
 - d) A preclinical solicitation will be distributed.

- 3) **CTEP Drug Development Plan – AMG479 (IGF-1R antibody; Helen Chen)**
 - a) CTEP is planning to add the IGF-1R antibody; AMG-479 to its portfolio (*further information is confidential*).
 - b) The IDSC endorsed the AMG-479 CTEP drug development plan without modifications.
 - c) Mass solicitation will be developed and distributed.

- 4) **Pharmacology TF – CYP Drug Interaction Guidance (Edward Newman):** Dr. Edward Newman presented the CYP drug interaction guidance and questions tackled by the Pharmacology TF in the process. During IDSC discussion it was deemed that the Pharmacology TF should reconvene and add a few more points to the guidance prior to submitting to CTEP.

- 5) **New Genomic Subject Expert Presentation (John Carpten):** Dr. John Carpten presented findings from Translational Genomics Research Institute (TGen) studies showing that a comprehensive genomic medicine approach can identify treatment options in advanced cancer patients. Results and lessons learned were showcased.

Non-Confidential

- 6) **CTEP Drug Development Plan – Blinatumomab AMG-103 (*anti-CD19 BiTE bispecific antibody*; Elad Sharon)**
 - a) CTEP is planning to add the anti-CD19 BiTE bispecific antibody; AMG-103 to its portfolio (*further information is confidential*).
 - b) The IDSC endorsed the AMG-103 CTEP drug development plan without modifications.
 - c) Mass solicitation will be developed and distributed.

- 7) **Redesign of the CTEP Early Phase Therapeutics Program (Zwiebel) – *further information on this topic is confidential*.**

- 8) **Future Plans/Calls/Meetings:**
 - a) **Next call:** TBD
 - b) **Fall 2012 CTEP EDD/IDSC Meeting:** Monday-Wednesday, October 15-17th, 2012 (Bethesda, MD – Natcher on NIH Campus)
 - c) **IDSC Winter 2013 Meeting:** Friday, January 11th in Chicago, IL
 - d) **Spring 2013 CTEP EDD/IDSC Meeting:** Monday-Wednesday, March 18-19, 2013 (Bethesda, MD – Natcher on NIH Campus)