

Public Summary
Investigational Drug Steering Committee (IDSC)
Tuesday, September 10, 2013

1) Call to Order, Introductions and Review of Minutes

- a) **Proposed motion # 1:** *The minutes from the April 23, 2013 IDSC meeting were approved.*
- b) **CTEP update (Zwiebel):** The CTEP Early Drug Development (EDD) meeting will be held annually in the Fall (**starting in 2014; October 20-22nd**). The Spring meeting (**March 10-11th, 2014**) will be reserved for U01 (soon to be UM1) and N01 grant and contract holder portfolio presentations. **IDSC meetings will still be held in conjunction with both meetings.**
- c) **CCCT update (Reeves):** The Winter (January 10, 2014) and Summer (July 18, 2014) IDSC meetings for 2014 will be held by Webinar.
- d) **Announcements:**
 - i) **Amit Oza will be the new IDSC N01 co-chair starting on January 1, 2014.** We thank Miguel Villalona for his service (term ends on December 31, 2013).
 - ii) **Miguel Villalona was presented with a plaque for his IDSC N01 co-chair service.**

2) Introduction to TRC-102 (BER inhibitor) presentation (Yves Pommier): Yves Pommier discussed the chemical composition of TRC-102 with IDSC members and other attendees.

3) CTEP Drug Development Plan for TRC-102 (Alice Chen):

- a) CTEP is planning to add the BER inhibitor; TRC-102 to its portfolio (*further information is confidential*).
- b) IDSC asked for modifications to the CTEP drug development plan following further input from subject matter experts.
- c) A mass solicitation for this agent will be devised by CTEP.

4) Introduction to BMN-673 (PARP 1 and 2 inhibitor) presentation (Shivaani Kummar): Shivaani Kummar discussed the clinical development of PARP inhibitors.

5) CTEP Drug Development Plan for BMN-673 (Alice Chen and Malcolm Smith):

- a) CTEP is planning to add the PARP 1 and 2 inhibitor; BMN-673 to its portfolio (*further information is confidential*).
- b) The IDSC endorsed the drug development plan without modification.
- c) Malcolm Smith (NCI/CTEP/CIB) presented the pediatric perspective for BMN-673 with Pediatric Preclinical Testing Program (PPTP) data.
- d) A mass solicitation for this agent will be devised by CTEP.

6) Pharmacology TF (Edward Newman):

- a) Edward Newman briefly discussed the draft CTEP Drug-Drug Interaction (DDI) Process document with the IDSC. Addition changes will be discussed between Pharmacology TF leaders, NCI CTEP Pharmaceutical Management Branch (PMB) staff, and CTEP IDB.
- b) A motion regarding developing a Pharmacology TF manuscript subcommittee to “**Standardizing Metabolism and Transport Drug Interaction Assessment in Oncology Clinical Trials**” was discussed. This project is an off-shoot from the Pharmacology TF DDI guidance document.
 - i) **Motion:** The Pharmacology Task Force requests authorization from the IDSC to form a writing committee to draft a manuscript entitled, “**Standardizing Metabolism and Transport Drug Interaction Assessment in Oncology Clinical Trials**”.
 - ii) The motion (# 4) was approved by IDSC members.

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- 7) **Biomarker/Clinical Trial Design TF:** A “Biomarker in Phase II Trials” meeting will be held on Monday-Tuesday, September 16-17th (2013) at the Bethesda North Marriott (North Bethesda, MD).
- 8) **Future Plans/Calls/Meetings for 2014:**
- a) IDSC Winter 2014 Meeting – Friday, January 10th (**WebEx only**)
 - b) UM1/N01 Annual and IDSC Spring 2014 Meeting: Monday-Tuesday, March 10-11th at Natcher or Building 31?
 - c) IDSC Summer 2014 Meeting – Friday, July 18th (**WebEx only**)
 - d) CTEP EDD Annual and IDSC Fall 2014 Meeting: Monday-Wednesday, October 20-22nd at Natcher (NIH Campus)

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