

Report of Ad hoc Subcommittee on Experimental Therapeutics

Daniel D. Von Hoff, MD FACP – Chair

Participants:

Dr. Daniel Von Hoff, Chair of the Subcommittee
Dr. Donald Coffey, NCAB
Dr. Lloyd Everson, NCAB
Dr. Waun Ki Hong, NCAB
Dr. Judith Kaur, NCAB
Mr. David Koch, NCAB
Dr. H. Kim Lyerly, NCAB
Dr. Karen Meneses, NCAB
Dr. Jennifer Pietenpol, NCAB
Dr. Carolyn Runowicz, NCAB
Dr. Joseph Tomaszewski, Subcommittee Executive Secretary
Dr. Robert Bird, NCI
Dr. Jerry Collins, NCI
Dr. James Doroshow, NCI
Dr. Leslie Ford, NCI
Dr. Suzanne Forry-Schaudies, NCI
Dr. Gary Kelloff, NCI
Dr. Mary K. Wolpert, NCI
Dr. David Bernstein, AACR
Ms. Andrea Collins, CMO, NCI
Dr. Marie Sweeney, NIOSH Nanci Hemberger (Writer, Scientific Consulting Group, Inc.)

1. Subcommittee met at 12:04pm June 22nd, 2010
2. Excellent attendance of 23 people (10 NCAB members)
3. Presentation given by Dr. Joseph E. Tomaszewski, Deputy Director Division of Cancer Treatment and Diagnosis (DCTD)
4. Briefly reviewed the history of the Developmental Therapeutics Review Group (DTRG)
 - In 1997 charged to examine/define NCI future with respect to development and discovery of new chemical and biological therapies for the treatment of patients with cancer
5. Reviewed how the NCI addressed each of the review recommendations
 - RAID program

- Drug Development Group (Created January 2000)
 - DCIDE Program (Created August 2000)
 - PD/Biomarker Program (Created July 2005)
 - Phase 0 Program (Created September 2005)
 - DCTD/CCR Joint Development Committee (Created September 2005)
 - Chemical Biology Consortium (Created August 2009)
 - NCI Experimental Therapeutics (NExT) Program (Created August 2009)
6. NCI RAID Program (our last review)
- 22 rounds – August 1998 to February 2009
 - 428 applications, 137 approved
 - 115 projects complete, 22 ongoing
 - 50 IND's filed
 - 41 agents licensed (>1650 patients treated)
 - Inspired clones in AIDS, etc
 - Merged into the NExT Program in August 2009
7. Drug Development Group
- Managed NCI Held IND's
 - Merged into the NExT Program in August 2009
8. DCIDE Imaging Program
- Contrast agents, molecular probes
 - Merged into the NExT Program in August 2009
9. Pharmacodynamic (PD)/Biomarker Program
- Pharmacodynamic Assay Development and Implementation Section
 - National Clinical Target Validation Laboratory progress on markers for DNA damage , γ -H2AX, Top1 cleavable complex)
 - Merged into the NExT Program in August 2009
10. Phase 0 Program
- Exploratory IND with no therapeutic intent (Maximum of 7 days)
 - Evaluated PARP inhibitor (ABT-888) in first Phase 0 in oncology; achieved 3 study goals with only 6 patients in 4 months
 - Merged into the NExT Program in August 2009
11. DCTD/CCR Joint Development Committee
- NCI academic partnership
 - 19 compounds/approaches
 - Merged into the NExT Program in August 2009
12. New Programs
- Chemical Biology Consortium (CBC) created to be the drug discovery component of NExT

Summary

We look forward to the NExT Program

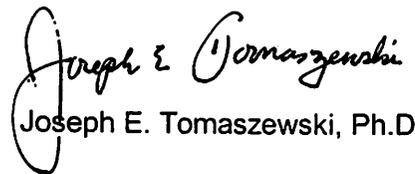
Questions

1. What new direction should NCI pursue
 - Simplify the systems (The NExT program should do that – note great leadership shown on that program today.)
 - Important motion Dr. Chabner
 - Mutations, deletions
 - Total sequencing
 - More defined models
 - (Engineered cells) not only NCI60
2. What is opinion of progress
 - Good and need to publish the success of program
3. What would be considered a measure of success?
 - # of IND's
 - Time to a go or no go decision - you have done your job
 - Use ratio of # approved over # evaluated – e.g. the success ratio

Respectfully submitted



Daniel D. Von Hoff, MD, FACP



Joseph E. Tomaszewski, Ph.D.