

Cancer Stem Cell Workshop: Status of CSC as Markers in Oncology

Max Wicha, University of Michigan, Chair

J. M. Jessup, CDP/NCI, Co-Chair

Overview:

This workshop is focused on facilitating the use of cancer stem cells (CSC) as markers of outcome and response to therapy. It will bring together 30 – 40 investigators to review the current status of CSC in clinical trials, to define the barriers for evaluating the CSC hypothesis and then to consider how to move the field forward. Since this workshop will focus on CSC as markers of prognosis and/or response, it will address the assays and technologies to reliably detect CSC and study designs for assessing clinical utility rather than on the biology and specific treatment of CSC. The workshop will focus on breast cancer and the leukemias and multiple myeloma in depth as paradigms for testing the stem cell hypothesis with experiences gleaned from other human malignancies. The workshop will also analyze in depth whether markers can be identified for individual tumor types and then whether optical imaging technologies are sufficiently reliable to support measurement of CSC in clinical samples. Finally, clinical trial designs that incorporate CSC along with the regulatory issues surrounding clearance or approval of CSC for clinical use will be studied. It is expected that the outcome of the workshop will be publications with recommendations for moving the field forward.

Goal:

The goal is to bring together investigators to assess the potential clinical utility of CSC as markers for prognosis and response to therapy in the practice of oncology.

Format: a day and a half meeting at the Neuroscience Center, Rockville MD, January 17 and 18, 2008.

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Agenda

Day One January 17, 2008

- 7:30 AM Registration and Light Breakfast
- 8:00 AM Welcome & Goals - Dr Jessup
- 8:10 AM Opening Remarks Dr. Niederhuber
- 8:20 AM Introductions All

Session 1

8:30 AM CSC in Human Breast Cancer

- Max Wicha, Session Chair

- 8:30 AM M. Wicha Evaluation of CSC in Breast Cancer
- 8:50 AM D. Hayes How to Evaluate CSC in the Clinic - the CTC Experience
- 9:10 AM J. Chang The CSC Response to Neoadjuvant Therapy
- 9:30 AM Discussion

10:00 AM **Break**

Session 2

10:30 AM CSC in Human Hematopoietic Malignancies

- Bill Matsui, Session Chair

- 10:30 AM J. Dick CSC in Human Leukemias: Models and Validation of the Stem Cell Hypothesis
- 10:50 AM F. Michor Mathematical Modeling of Stem Cell Responses to Therapy
- 11:10 AM W. Matsui CSC in Human Multiple Myeloma: Validation of CSC Under Clinical Conditions
- 11:30 AM Discussion

12:00 Noon Lunch (on your own)

Session 3

1:00 PM **Advantages/Disadvantages of Assays and Models for Human Stem Cells**

- Peter Dirks, Session Chair

1:00 PM	Peter Dirks	Human CSC in Glioblastoma
1:20 PM	D. Simeone	Human CSC in Pancreas Cancer
1:40 PM	D. Tang	Human CSC in Prostate Cancer
2:00 PM	C. O'Brien	Human CSC in Colon Cancer
2:20 PM	S. Gambhir	PET and Other Imaging Models for Human CSC
2:40 PM	M. F. Clarke	Models to define Human CSC
3:00 PM	W. El-Deiry	Imaging of CSC in Animal Models
3:20 PM	Discussion	
3:40 PM	Break	

Session 4

4:00 PM **Methods to Identify CSCs in Clinical Specimens - Flow Cytometry**

- S. Tanner, Session Chair

4:20 PM	G. Nolan	Use of Flow Cytometry to Identify Human CSC
4:40 PM	S. Tanner	MS Meets Flow Cytometry (I know, need a formal title)
5:00 PM	Discussion	
5:30 PM	Adjourn	

Day Two - January 18, 2008

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Agenda (Cont'd)

7:30 AM Light Breakfast

Session 5

8:00 AM **Methods to Identify CSCs in Clinical Specimens - Tissue Imaging**

- Max Loda, Session Chair

8:00 AM D. Rimm Multiparameter Tissue Imaging To Identify Cell Subsets in Human Tissues

8:20 AM M. Loda Detection of CSC by Multiplex Spectral Imaging

8:40 AM S. Nie Reproducibility of Multiplex Spectral Imaging

9:00 AM D. Farkas Issues with Evaluation of Cell Subsets by Multiplex Spectral Imaging

9:20 AM R. Cote Imaging of Metastatic Precursor Cells

9:40 AM Discussion

10:00 AM Break

Session 6

10:30 AM **Design of Clinical Trials to Measure Numbers of CSC**

- Kim Jessup, Session Chair

10:30 AM D. Berry Adaptive Design of Trials involving Cancer Stem Cells as Markers

10:50 AM R. Becker/ N. Hanna OIVD/CDRH Evaluation Criteria for In Vitro Devices/Assays

11:10 AM R. Sridhara CDER's Evaluation of Predictive Markers

11:30 AM R. Dagher CDER's Evaluation of Response and Surrogate Markers

11:50 AM L. McShane Marker Development & Trial Designs to test CSC

12:10 PM Discussion

12:30 PM Wrap-Up and Next Steps

1 PM Adjourn