

**Breast Cancer Steering Committee
Clinical Trials Planning Meeting
Next Generation Phase III Studies for HER2-Positive Breast Cancer
Monday and Tuesday, May 16-17, 2011**

****The Legacy Hotel, Rockville, MD**
1775 Rockville Pike, Rockville, MD 20852, (301) 881-2300**

Meeting Goal: The goal of this Clinical Trial Planning Meeting is to address key questions regarding the resistance to HER2 targeting, to discuss HER2-targeted drugs (including new agents), to discuss other drugable targets in HER2-positive breast cancer, and to recommend directions for future clinical trials in the treatment of HER2-positive breast cancer.

DAY 1: MONDAY, MAY 16, 2011

11:30 AM – 12:00 PM REGISTRATION

12 PM WORKING LUNCH

12:00 – 12:05 PM Welcome and Introduction to the NCI Clinical Trials Planning Meeting
Nancy Davidson and Charles Geyer, BCSC Co-Chairs

12:05 – 12:15 PM Charge for the Clinical Trials Planning Meeting
Lisa Carey and Mark Pegram, BCSC HER2 CTPM Planning Committee Co-Chairs

**12:15 – 1:50 PM SESSION 1: BASIC AND CORRELATIVE SCIENCE AND KEY PATHWAYS FOR
HER2-POSITIVE BREAST CANCER**
Moderator: Laura Van't Veer

(12:15 - 12:40) **Refresher: Basic biology, relevant pathways, and drug classes**
Mark Pegram and Neil Spector

(12:40 - 12:55) **Questions and Discussion**

(12:55 – 1:25) **HER2+ behavior in the trastuzumab adjuvant era**
Edith Perez and Charles Geyer

(1:25 – 1:35) **Site-specific tropism – CNS**
Nancy Lin

(1:35 – 1:50) **Questions and Discussion**

1: 50 – 3:15 PM

SESSION 2: STANDARDIZE AND GENERALIZE METHODOLOGY

Moderator: Craig Allred

- (1:50 - 2:10) **Review currently available measures of HER-2 (ASCO/CAP)**
Michael Press
- (2:10 - 2:30) **Concordance/discordance issues from HER2 testing: Clinical experience**
Antonio Wolff
- (2:30 – 2:50) **Review of predictive marker study results from NSABP trial B-31**
Soon Paik
- (2:50 – 3:15) **Questions and Discussion**

3:15 - 3:30 PM

BREAK

3:30 – 4:50 PM

SESSION 3: CLINICAL TRIALS EXPERIENCE IN HER2-POSITIVE BREAST CANCER – LESSONS LEARNED AND CURRENT PORTFOLIO

Moderator: Kimberly Blackwell

- (3:30 – 3:45) **Prior and current phase 3 studies: International**
Gunter von Minckwitz
- (3:45 – 3:55) **Prior and current phase 3 studies: North American**
Jo Anne Zujewski
- (3:55 – 4:10) **Statistical designs and endpoints of phase 3 trials**
Kenneth Hess
- (4:10 – 4:25) **Optimizing tissue collection for correlative science**
Brian Leyland-Jones
- (4:25 – 4:50) **Questions and Discussion**

4:50 – 6:15 PM

SESSION 4: ISSUES FOR FUTURE TRIALS

Moderators: Ruth O'Regan and Liz Frank

- (4:50 – 5:05) **HER2-resistance**
Ian Krop
- (5:05 – 5:30) **Novel HER2-targeted agents in development – phase 1 and 2 studies**
Francisco Esteva
- (5:30 – 5:45) **Choice of chemotherapy backbone**
Stacy Moulder
- (5:45 – 6:00) **Endocrine options and implications of ER cross talk**
Kent Osborne
- (6:00 – 6:15) **Combination targeting of HER2-signaling pathways**
Ruth O'Regan

(6:15 – 6:30) **Planning for and managing toxicities**
Hope Rugo

6:30 – 6:45 PM BREAK

6:45 PM WORKING DINNER – PREPARATION FOR DAY 2
Moderators: Lisa Carey and Mark Pegram

SESSION 4 (continued): Panel discussion

Continued discussion: Logistical issues, biomarker challenges, barriers to success, and accrual issues

DAY 2: TUESDAY, MAY 17, 2011

7:15 – 8:00 AM Coffee

8:00 – 8:05 AM Welcome and Charge
Nancy Davidson and Charles Geyer, BCSC Co-Chairs

8:05 – 8:10 AM Summary of Day 1
Lisa Carey and Mark Pegram, BCSC HER2 CTPM Planning Committee Co-Chairs

8:10 – 8:40 AM Integration of current trials with unmet needs

- **Settings**
 - Neoadjuvant vs. adjuvant vs. metastatic
- **Approach**
 - Chemo-based vs. endocrine-based vs. all biologics

Eric Winer

8:40 – 9:00 AM Questions and Discussion

9:00 AM – 2:30 PM SESSION 5: DEVELOPMENT OF FUTURE TRIALS
Moderators: Nancy Davidson and Charles Geyer

(10:00 – 10:15 AM) **MORNING BREAK**

(12:15 PM) **WORKING LUNCH**

2:30 – 3:00 PM Meeting Summary and Future Directions
Nancy Davidson, Charles Geyer, Lisa Carey, and Mark Pegram