



BREAST

DISEASE SITE COMMITTEE MEETING AGENDA

Chelsea Hotel, Toronto, Ontario

ROOM: **Mountbatten Salon** Saturday April 30, 2016: 8:00 AM – 12:00 PM

CO-CHAIRS: **T. WHELAN / K. GELMON**

CME Credits:

Credits for Specialists: This event is an Accredited Group Learning Activity (Section 1) as defined by the Maintenance of Certification program of the Royal College of Physicians and Surgeons of Canada, and approved by Queen's University.

Learning Objectives:

- To understand and address, through clinical and translational research, the disease burden associated with breast cancer both in the adjuvant and the metastatic setting in Canada
- To review recent developments in the understanding of molecular biology, new therapeutics and clinical trial methodology as these relate to breast cancer
- To update, review, and discuss recent results of clinical studies conducted by or in collaboration with Canadian Cancer Trials Group
- To place the results of clinical studies in the context of ongoing care of patients in Canada with breast cancer and to translate these results into clinical practice
- To provide a learning environment supportive to investigators
- To provide mentoring opportunities for investigators new to clinical research

8:00am	Welcome & Review of Morning's Objectives
8:05am	CCTG Presentations for ASCO / 2015 Publications
8:15am	Update from the IND Committee
8:35am	Approved Studies Pending Activation
9:00am	Studies Open to Accrual
9:45am	News from Closed/Analyzed Studies
10:15am	Coffee
10:30am	Summary of 2016 APR 28 Retreat / Potential New Studies
11:10am	Update of Biobank Inventory and Ongoing Correlative Proposals
11:20am	Update on Survivorship Committee Activities
11:30am	CCSRI Grant Application and Strategic Planning
11:50am	Other Business
12:00	Adjournment

Appendix I – Agenda Details

Objectives

CCTG Presentations for ASCO / 2015 Publications (see posted list)

Update from the IND Committee (Phil Bedard)

- **IND229** - A Phase 1b Pharmacodynamic Study of Durvalumab (MEDI4736) in Patients with HER-2 Positive Metastatic Breast Cancer (MBC) Receiving Trastuzumab (**Study Chair: Stephen Chia**)
- **IND230** - A Phase II Trial of Durvalumab and Tremelimumab in Pretreated, Metastatic or Locally Refractory Estrogen Receptor Positive, HER2-Negative Breast Cancer
- **IND231** - A Phase I/II Study of CX5461 (**Study Chair: John Hilton**)

Approved Studies Pending Activation

- **MA37** (PALLAS - PALbociclib CoLLaborative Adjuvant Study: A Randomized Phase III Trial of Palbociclib with Adjuvant Endocrine Therapy versus Endocrine Therapy Alone for Hormone Receptor Positive (HR+)/ Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Early Breast Cancer) (**Julie Lemieux**)
- **MAC.20** - Randomized Phase III Trial Evaluating the Role of Weight Loss In Adjuvant Treatment of Overweight and Obese Women with Early Breast Cancer (**Vanessa Bernstein**)
- **MAX1** - Long term Anastrozole vs Tamoxifen Treatment Effects (LATTE) (**Lois Shepherd**)

Studies Open to Accrual

- **I213** - A Randomized Phase II Study of Reolysin For Patients Receiving Standard Weekly Paclitaxel Therapy as Therapy For Advanced/Metastatic Breast Cancer (**Susan Ellard / Vanessa Bernstein**)
- **MA.36** - A Randomised, Double-Blind, Parallel group, Placebo-Controlled Multicenter Phase III Study to Assess the Efficacy and Safety of Olaparib versus Placebo as Adjuvant Treatment in Patients with Germline BRCA1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy (**Andrea Eisen**)
- **MA.38** - Randomized Phase II Study Comparing Two Different Schedules of Palbociclib plus Second Line Endocrine Therapy in Women with Estrogen Receptor Positive, HER2 Negative Advanced/Metastatic Breast Cancer (**Anil Joy**)
- **MAC18** - POSITIVE: A Study Evaluating the Pregnancy Outcomes and Safety of Interrupting Endocrine Therapy for Young Women with Endocrine Responsive Breast Cancer who Desire Pregnancy (**Ellen Warner**)
- **MAC.19** - A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1 -3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy (**Steven Latosinsky**)
- **REaCT** – Successful Design and Implementation of Pragmatic Practice Changing Clinical Trials (**Mark Clemons**)

News from Closed/Analyzed Studies

- **MA.17R** - A Double Blind Randomization to Letrozole or Placebo for Women Previously Diagnosed with Primary Breast Cancer Completing Five Years of Adjuvant Aromatase Inhibitor Either as Initial Therapy or After Tamoxifen (Including Those in the MA.17 Study) (**Paul Goss / Wendy Parulekar**)
- **MA.32** - A Phase III Randomized Trial of Metformin versus Placebo on Recurrence and Survival in Early Stage Breast Cancer (MA.32D remains open to accrual for ER/PgR negative Patients) (**Pamela Goodwin**)

Summary of 2016APR28 Retreat / Potential New Studies (Karen Gelmon / Tim Whelan)

Update of Biobank Inventory and Ongoing Correlative Proposals (Lois Shepherd)

Update on Survivorship Committee Activities (Karen Gelmon / Harriet Richardson)

CCSRI Grant Application and Strategic Planning (Karen Gelmon / Tim Whelan)

Other Business