**DISEASE SITE COMMITTEE MEETING AGENDA**

**Chelsea Hotel, Toronto, Ontario**

**ROOM:** Mountbatten Salon  
Saturday April 29, 2017: 8:00 AM – 12:00 PM

**CO-CHAIRS:** T. Whelan / K. Gelmon

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**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 review the rationale and study requirements for emerging technologies with an emphasis on TMIST, a new study (Tomosynthesis Mammographic Imaging Screening Trial (TMIST) ECOG-ACRIN EA1151)
- 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

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8:00am  
Welcome & Review of Morning’s Objectives

8:05am  
CCTG Presentations for ASCO / 2016Publications

8:15am  
Update from the IND Committee

8:45am  
Approved Studies Pending Activation

9:30am  
Studies Open to Accrual

10:15am  
Coffee

10:30am  
News from Closed/Analyzed Studies

10:45am  
TMIST/Martin Yaffe

11:15am  
Summary of 2017APR27 Retreat / Potential New Studies

11:30am  
Stand Up to Cancer/Phil Bedard

11:40am  
CCSRI Grant Application and Strategic Planning

11:50am  
Other Business

12:00  
Adjournment
Appendix I – Agenda Details

Objectives

CCTG Presentations for ASCO / 2016 Publications (see posted list)

Update from the IND Committee (Phil Bedard to introduce)

- IND213 - A Randomized Phase II Study of Reolysin For Patients Receiving Standard Weekly Paclitaxel Therapy as Therapy For Advanced/Metastatic Breast Cancer (S. Ellard / V. Bernstein)
- IND214 - A Phase I/II Study of MG1 Maraba/MAGE-A3 (MG1MA3), With and Without Adenovirus Vaccine, With Transgenic MAGE-A3 Insertion (AdMA3) in Patients with Incurable Advanced/Metastatic MAGE-A3-Expressing Solid Tumours (S. Ellard / V. Bernstein)
- IND229 - A Phase 1b Pharmacodynamic Study of Durvalumab (MEDI4736) in Patients with HER-2 Positive Metastatic Breast Cancer (MBC) Receiving Trastuzumab (S. Ellard / V. Bernstein)
- IND230 - A Phase II Trial of Durvalumab and Tremelimumab in Pretreated, Metastatic or Locally Refractory Estrogen Receptor Positive, HER2-Negative Breast Cancer (S. Ellard / V. Bernstein)
- IND231 - A Phase I/II Study of CX5461 (S. Ellard / V. Bernstein)

Approved Studies Pending Activation

- MAC.21 - Aspirin for Breast Cancer (ABC): Randomized Trial of Aspirin as Adjuvant Therapy for Node Positive Breast Cancer (M. Salim)
- MA.39 - Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive Breast Cancer (T. Whelan)
- CAPTUR - Canadian Profiling and Targeted agent Utilization trial (CAPTUR) a Phase II Basket Trial

Studies Open to Accrual

- 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 (A. Eisen)
- 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 (J. Lemieux)
- 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 (E. Warner)
- MA.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 (S. Latosinsky)
- MAC.20 - Randomized Phase III Trial Evaluating the Role of Weight Loss In Adjuvant Treatment of Overweight and Obese Women with Early Breast Cancer (V. Bernstein)

News from Closed/Analyzed Studies

- 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) (P. Goodwin)
- MA.34 (Aphinity) - A Randomized Multicenter, Double-Blind, Placebo-Controlled Comparison of Chemotherapy Plus Trastuzumab Plus Placebo versus Chemotherapy Plus Trastuzumab Plus Pertuzumab as AdjuvantTherapy in Patients with Operable HER2-Positive Primary Breast Cancer (S. Dent)
- 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 (A. Joy)

Summary of 2017APR27 Retreat / Potential New Studies (K. Gelmon / T. Whelan)

- LA LEAST: Luminal A- Less Endocrine Adjuvant Systemic Therapy: Limited Hormone Therapy after Low Risk Hormone Receptor Positive, HER2 Negative BC (C. Lohrisch)
• The Canadian F.I.G.H.T. (Fluorescence Image-Guided Help in Treating) Breast Cancer Surgical Trial (Ralph DaCosta)
• Alliance A221505: A Phase III Randomized Trial of Hypofractionated Post Mastectomy Radiation with Breast Reconstruction (Iwa Kong)

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

Other Business