NCIC CLINICAL TRIALS GROUP

BREAST

DISEASE SITE COMMITTEE MEETING AGENDA

Eaton Chelsea Hotel, Toronto, Ontario

ROOM: Mountbatten Salon Saturday May 2, 2015: 8:00 AM – 2:30 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 current results of clinical studies conducted by or in collaboration with NCIC Clinical 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 Objectives T.Whelan/K.Gelmon

8:05am Proposals

8:05am CTEP Proposals
• Phase III Randomized Trial Of Hypofractionated Post Mastectomy Radiation (Alliance) T.Whelan
• The Impact Of Weight Loss On Outcomes In Early Breast Cancer (A011201) P.Goodwin

8:25am BIG Proposals
• PALLAS - PALbociclib CoLlaborative Adjuvant Study: “Double blind phase 3 trial of Palbociclib or placebo with adjuvant endocrine therapy for HR+/HER2- breast cancer (ABCSG-42 BIG-03/14) K.Gelmon
• ASTER 2 - Adjuvant Systemic Therapy, HER2+, women > 70: “chemo-free” regimen with dual anti-HER2 blockade versus standard treatment trastuzumab + chemotherapy K. Gelmon

8:45am Other New Proposals / Proposals in Development
• LORIS – Phase III, Surgery vs Active Monitoring, Low Risk DCIS (Univ.Birmingham) N.LookHong
• LATTE - Long-Term Anastrozole vs. Tamoxifen Treatment Effects (MA.37) (QMUL) L.Shepherd
• CONQUER - Cisplatin/Radiotherapy to Overcome Resistance to Standard Neoadjuvant therapy: a QUEst for Response J.F.Boileau

9:15am IND Trials:
• IND.213 (Phase II Reolysin/Paclitaxel in Advanced/Metastatic) S.Ellard/V.Bernstein
9:25am  Trials Opening Soon / Recently Opened

- MAC.17 - SWOG 1207 (Phase III Endocrine Therapy +/- Everolimus, High Risk)  K.Gelman
- MA.36 - BIG 6-13 (Phase III Olaparib vs placebo, adjuvant, in BRCA1/2 mutations + high risk HER2-) A. Eisen
- IBCSG 48-14 / BIG 8-13 POSITIVE (Pregnancy Outcomes & Safety of Interrupting endocrine therapy for young women with endocrine responsive breast cancer who desire pregnancy) E. Warner
- MA.32D – (Change in Mammographic Density with Metformin Use – Alliance A211201) P.Goodwin

10:15am  Coffee

10:30am  CTSU Trials:

- MAC.9  (SWOG S0307 - Phase III, Bisphosphonates, Adjuvant Therapy, Primary Breast Cancer) M.Clemons
- MAC.12  (ECOG PACTT-1 - Individualized Options For Treatment: The TAILORx Trial) K.Pritchard
- MAC.14  (ECOG 2108 – Local Therapy in Stage IV) M.Basik
- MAC.15  (SWOG S1007 – Responder Trial) S.Chia/B.Dhesy

11:10am  Invited Speaker: Dr. Clifford A. Hudis

_Hormone Receptor Positive Metastatic Breast Cancer - Meaningful Improvements and Useful End Points_

12:00 Noon  Lunch

1:30pm  NCIC CTG Proposals:

- **PALBO** – Randomized Phase II Study Comparing Two Different Schedules of Palbociclib in Women with Metastatic Disease in First Line Setting W.Parulekar/L.Shepherd
- **ADAPT** - Advanced Diagnostics/Personalized Treatment Project to accelerate drug development and improve outcome for Triple Negative Breast Cancer S.Verma
- Pre-operative Predictor **Biomarker Study** in Women with Early, Receptor Positive Breast Cancer M.Basik
- **STAND UP TO CANCER** – Theranostic Biomarker Study in Luminal Breast Cancer J.Bartlett/W.Parulekar
- **I-SPY-3** Phase 3 Pre-operative Efficacy testing of New Drugs in Women with HER2+ Disease W.Parulekar

2:15pm  Trials with Pending Results / Closed Trials:

- **MA.17R** (Letrozole vs Placebo after AI) W.Parulekar
- **MA.20** (Regional Radiation Therapy in Early Breast Cancer) T. Whelan
- **MA.32** (Metformin + NSABP Fatigue MA.32F) P.Goodwin
- **MA.33** (TROG 07.01: Non-low risk DCIS of breast) I.Olivotto
- **MA.34** (BIG 4-11/APHINITY/Pertuzumab) S.Dent

2:30pm  Closing Remarks & Adjournment