

BREAST DISEASE SITE COMMITTEE MEETING

CHELSEA HOTEL, TORONTO, ON
ROOM: MOUNTBATTEN SALON
SATURDAY MAY 4, 2024, 8:00 AM – 12:00 PM

CO-CHAIRS : S.CHIA / E. RAKOVITCH
SENIOR INVESTIGATORS: L. SHEPHERD / W. PARULEKAR

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:

- Identify and address, through clinical trial and translational research, the disease burden associated with breast cancer in Canada.
- Identify clinical trial research opportunities within the Canadian Cancer Trials Group.
- Integrate current knowledge regarding therapeutics and tumour biology in trial concept development and conduct.
- Apply best practices in clinical trials conduct and analysis to the Canadian Cancer Trials Group research agenda.
- To identify mentoring opportunities within the Canadian Cancer Trials Group research agenda for new investigators.
- To synthesize, disseminate, exchange, and apply knowledge derived from clinical trials to improve the health of Canadians.

8:00am	Welcome & Review of Morning's Objectives (Feedback, Recognition of centres with high accrual)
8:15am	Update: Publications/Abstracts 2023-2024
8:25am	Update from the IND Committee
8:50am	Approved Studies Pending Activation
9:05am	Studies Open to Accrual
10:15am	Coffee
10:30am	News from Closed/Analyzed Studies
11:00am	Potential New Studies
11:15am	Presentation Liquid Biopsies in Breast Cancer - Stephen Chia
11:45am	Other Business
12:00pm	Meeting Adjourned

Appendix I – Agenda Details

Objectives

CCTG Presentations for ASCO / 2023/2024 Publications

Update from the IND Committee (Phil Bedard to introduce)

Approved Studies Pending Activation:

- **NRG BR009** - A Phase III Adjuvant Trial Evaluating the Addition of Adjuvant Chemotherapy to Ovarian Function Suppression plus Endocrine Therapy in Premenopausal Patients with pN0-1, ER-Positive/HER2-Negative Breast Cancer and an Oncotype Recurrence Score ≤ 25 (OFSET) **S. Chia**



Open Trials:

- **IND.241** - A Liquid-biopsy Informed Platform Trial to Evaluate Treatment in CDK4/6-inhibitor Resistant ER+/HER2- Metastatic Breast Cancer - **P. Bedard**
- **IND.243** - A Phase II Study of RP-6306 in Patients with Advanced Cancer - **P. Bedard**

Studies Open to Accrual

- **MA.39 - Tailor RT:** A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive Breast Cancer - **T. Whelan**
- **MA.40** - A Double-Blind Placebo Controlled Randomized Phase III Trial of Fulvestrant and Ipatasertib as Treatment for Advanced HER-2 Negative and Estrogen Receptor Positive (ER+) Breast Cancer Following Progression on First Line CDK 4/6 Inhibitor and Aromatase Inhibitor (FINER) - **S. Chia**
- **MAC.22 / TMIST** - ECOG-ACRIN EA1151 Tomosynthesis Mammographic Imaging Screening Trial (TMIST) - **L. Shepherd**
- **MAC.26 (S1706)** - A Phase II Randomized Trial of Olaparib (NSC-747856) Administered Concurrently with Radiotherapy versus Radiotherapy Alone for Inflammatory Breast Cancer - **E. Rakovitch**
- **MAC.27 / A011801** - COMPASSHER2 Residual Disease (RD), A Double-Blinded, Phase III Randomized Trial of T-DM1 and Placebo Compared with T-DM1 and Tucatinib - **P. Blanchette**
- **MAC.28 / NRG BR007** - A Phase III Clinical Trial Evaluating De-escalation of Breast Radiation for Conservative Treatment of Stage 1, Hormone Sensitive, HER2-Negative, Oncotype Recurrence Score \leq 18 Breast Cancer (DEBRA) - **V. Theberge**
- **MAC.29/A012103/OptimICE-pCR** - De-escalation of Therapy in Early-Stage TNBC Patients who Achieve pCR after Neoadjuvant Chemotherapy with Checkpoint Inhibitor Therapy - **S. Chia**

News from Closed to Accrual Studies

- **MAC.19 (A011202)** - 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 (A011401)** - Randomized Phase III Trial Evaluating the Role of Weight Loss In Adjuvant Treatment of Overweight and Obese Women with Early Breast Cancer - **V. Bernstein**
- **MAC .23 (A221505):** A Phase III Randomized Trial of Hypofractionated Post Mastectomy Radiation with Breast Reconstruction - **I. Kong**
- **MAC.24 (SWOG 1418)** - A Randomized, Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer with > 1 cm Residual Invasive Cancer or Positive Lymph Nodes (pN1) After Neoadjuvant Chemotherapy - **S. Chia**
- **MAC.25 (NRG-BR1751)** - Randomized, Double-Blind, Phase III Trial of Paclitaxel/Trastuzumab/Pertuzumab with Atezolizumab or Placebo in First-Line HER2 Positive Metastatic Cancer - **S. Chia**

Potential New Studies

- **SCARLET/SWOG S2212** – Shorter Anthracycline-free Chemoimmunotherapy Adapted to pathological Response in Early TNBC – **S. Chia**
- **NoLEEta** – No chemotherapy in intermediate-risk HR+ HER2- early breast cancer treated with Ribociclib (LEE-011) in the adjuvant setting, a non-inferiority Phase III trial – **S. Chia**
- **Recurrence study** – **S. Chia**

Other Business



List of Publications 2023-2024

Breast Publications 1 January 2023 – 13 March 2024

1. (EBCTCG), E.B.C.T.C.G., et al., Radiotherapy to regional nodes in early breast cancer: an individual patient data meta-analysis of 14,324 women in 16 trials. *The Lancet*, 2023. 402(10416): p. 1991-2003.
2. Agostinotto, E., et al. The impact of drug-drug interactions between palbociclib and proton pump inhibitors on clinical outcomes of patients with hormone receptor positive, HER2-negative, early breast cancer: an exploratory analysis of the PALLAS study. in *San Antonio Breast Cancer Symposium*. 2023. San Antonio, TX. Ref Type: Abstract
3. Azim, H., et al. Fertility preservation and assisted reproductive technologies (ART) in breast cancer (BC) patients (pts) interrupting endocrine therapy (ET) to attempt pregnancy. in *San Antonio Breast Cancer Symposium*. 2023. San Antonio, TX. Ref Type: Abstract
4. Chapman, J.A., et al. Adjunctive statistical standardization of quantitated machine image analysis of Estrogen and Progesterone Receptors: CCTG MA.27 trial. in *San Antonio Breast Cancer Symposium*. 2023. San Antonio, TX. Ref Type: Abstract
5. Chumsri, S., et al. MHC Class I and II Expression, Functional Tertiary Lymphoid Structure (TLS), and Outcomes in Early-Stage HER2-Positive (HER2+) Breast Cancer in NCCTG N9831 (Alliance). in *San Antonio Breast Cancer Symposium*. 2023. San Antonio, TX. Ref Type: Abstract
6. Connolly, R.M. and K.D. Miller, Back to the Beginning: The Role of Ovarian Suppression in Management of Hormone Sensitive Breast Cancer in Premenopausal Women. *Journal of Clinical Oncology*, 2023. 41(7): p. 1339-1341.
7. Early Breast Cancer Trialists' Collaborative, G., Anthracycline-containing and taxane-containing chemotherapy for early-stage operable breast cancer: a patient-level meta-analysis of 100,000 women from 86 randomised trials. *The Lancet*, 2023. 401(10384): p. 1277-1292.
8. Francis, P.A., et al., Adjuvant Endocrine Therapy in Premenopausal Breast Cancer: 12-Year Results From SOFT. *Journal of Clinical Oncology*, 2023. 41(7): p. 1370-1375.
9. Goodwin, P.J., et al., Effect of Metformin Versus Placebo on New Primary Cancers in Canadian Cancer Trials Group MA.32: A Secondary Analysis of a Phase III Randomized Double-Blind Trial in Early Breast Cancer. *Journal of Clinical Oncology*, 2023. 41(35): p. 5356-5362.
10. Kantor, O., et al. Racial and Ethnic Differences in Clinical Outcomes among North American Patients with Hormone Receptor-Positive, HER2-negative, Early Breast Cancer in the PALLAS Trial (AFT-05). in *San Antonio Breast Cancer Symposium*. 2023. San Antonio, TX. Ref Type: Abstract
11. Ligibel, J.A., et al. Effect of a telephone-based weight loss intervention (WLI) on weight at 12-months in women with early breast cancer: Results from the Breast Cancer Weight Loss (BWEL) trial. in *Journal of Clinical Oncology*. 2023. Ref Type: Abstract
12. Luen, S.J., et al., Genomic characterisation of hormone receptor-positive breast cancer arising in very young women. *Annals of Oncology*, 2023. 34(4): p. 397-409.
13. Nader-Marta, G., et al. Clinical characterization, prognostic and predictive values of HER2-low in early breast cancer in the PALLAS trial. in *San Antonio Breast Cancer Symposium*. 2023. San Antonio, TX. Ref Type: Abstract
14. Paganì, O., et al., Adjuvant Exemestane With Ovarian Suppression in Premenopausal Breast Cancer: Long-Term Follow-Up of the Combined TEXT and SOFT Trials. *Journal of Clinical Oncology*, 2023. 41(7): p. 1376-1382.
15. Partridge, A.H., et al., Interrupting Endocrine Therapy to Attempt Pregnancy after Breast Cancer. *New England Journal of Medicine*, 2023. 388(18): p. 1645-1656.
16. Pfeiler, G., et al., Impact of BMI in Patients With Early Hormone Receptor-Positive Breast Cancer Receiving Endocrine Therapy With or Without Palbociclib in the PALLAS Trial. *Journal of Clinical Oncology*, 2023. 41(33): p. 5118-5130.
17. Shao, D., et al. Computer analysis of nuclear morphology with Multiple Instance Learning Predicts Overall Survival for Node Positive Breast Cancer Patients from SWOG S8814: A Blinded Validation Study. 2023. Ref Type: Abstract
18. Shenasa, E., et al. Digital profiling of immune biomarkers: Relation to anthracycline benefit. in *ESMO Breast Cancer Congress*. 2023. Berlin: *Annals of Oncology*. Ref Type: Abstract
19. Sparano, J., et al. Trial Assigning Individualized Options for Treatment (TAILORx): An Update Including 12-Year Event Rates. 2023. Ref Type: Abstract
20. Speers, C.W., et al., Evaluation of the Sensitivity to Endocrine Therapy Index and 21-Gene Breast Recurrence Score in the SWOG S8814 Trial. *Journal of Clinical Oncology*, 2023. 41(10): p. 1841-1848.
21. Spring, L.M., et al. HER2-19 Impact of HER2 low status on clinical outcomes in participants with 1-3 positive lymph nodes, HR+/HER2- breast cancer with recurrence score </25 randomized to endocrine therapy +/- chemotherapy: results from SWOG S1007 (RxPONDER). 2023. Ref Type: Abstract
22. Stover, D., et al. Protocol-defined biomarker analysis in the PALLAS (AFT-05) adjuvant trial: Genomic subtype derived from RNA sequencing of HR+/HER2- early breast cancer. in *San Antonio Breast Cancer Symposium*. 2023. San Antonio, TX. Ref Type: Abstract
23. Tolaney, S., et al. OptimICE-pCR: De-escalation of therapy in early-stage TNBC patients who achieve pCR after neoadjuvant chemotherapy with checkpoint inhibitor therapy (Alliance A012103). in *San Antonio Breast Cancer Symposium*. 2023. San Antonio, TX. Ref Type: Abstract

