

## GENITOURINARY

CHELSEA HOTEL, TORONTO, ON  
ROOM: WREN

SATURDAY APRIL 29TH, 2023, 8:00AM – 1:30 PM

CHAIR: SEBASTIEN HOTTE  
CO-CHAIRS: TAMIM NIAZI AND WASSIM KASSOUF  
SENIOR INVESTIGATORS: MARIAM JAFRI and WENDY PARULEKAR  
STUDY COORDINATOR: AKUNNE NDIKA

### 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 genitourinary malignancies 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 Genitourinary Disease Site Committee Research agenda
- To provide a learning and mentoring environment supportive to new investigators

<b>8:00 am</b>	<b>GU Workshop</b>	<b>M. Kolinsky, A. Wyatt, H. Feilotter</b>
<b>9:45 am</b>	<b>Coffee Break</b>	
<b>10:00 am</b>	<b>Main Meeting - Welcome</b>	<b>S. Hotte</b>
<b>10:10 am</b>	<b>New Trial Concepts</b>	
	Doublet vs. Triplet Therapy for Patients with High Volume Metastatic Castration Sensitive Prostate Cancer	<b>K. Chi</b>
	TRIPLE-SWITCH Trial Concept	<b>M. Ong</b>
	RECURrent prostate cancer: limited vs eXtended-field (RECURx)	<b>M. Barkati</b>
	A randomized Phase 2 clinical trial evaluating different séquencent strategies of bipolar androgen deprivation therapy (BAT) and darolutamide for the treatment of mCRPC	<b>A. Rose</b>
	Phase III Randomized Trial of Stereotactic ablative radiotherapy (SAbR) for Oligometastatic Advanced Renal Carcinoma ( <b>SOAR</b> )	<b>P. Cheung</b>
	A phase I feasibility and safety study of GCAR1, a chimeric antigen receptor (CAR) T cell therapy for patients with relapsed/refractory GPNMB expressing solid tumors	<b>J-W. Henning</b>



	<b>PAPMET2 (S2200):</b> First line Cabozantinib vs Cabozantinib+ Atezolizumab in metastatic papillary RCC	<b>D. Bosse</b>
	A Randomized Phase III Trial of Intravesical BCG verSus Intravesical Docetaxel and GEmcitabine Treatment in BCG Naïve High Grade Non-Muscle Invasive Bladder Cancer ( <b>BRIDGE</b> )	<b>M. Jafri</b>
<b>11:30 am</b>	Guest Speaker Theranostics in prostate cancer - clinical applications and potential opportunities	<b>O. Sartor</b>
<b>12:10 pm</b>	Q & A	
<b>12:30 pm</b>	<b>Approved Trials: Pending Activation</b> <b>ASCENDE-SBRT:</b> Androgen Suppression Combined with Elective Nodal and a Dose Escalated Boost. A Non-Inferiority, Phase 3 Randomized Controlled Trial of Stereotactic Body Radiation Therapy versus Brachytherapy Boost	<b>A. Loblaw</b>
	A trial investigating platinum and taxane chemotherapy in metastatic castration resistant prostate cancer patients with alterations in DNA damage response genes	<b>M. Kolinsky</b>
	A randomized phase II trial evaluating the impact of SBRT with or without Niraparib in patients with metastatic hormone sensitive prostate cancer treated with ADT and androgen axis directed therapy	<b>T. Niazi &amp; S. Hotte</b>
<b>12:45 pm</b>	<b>Ongoing Trials: Open to Accrual</b> <b>BLC.5 MAIN-CAV (A032001):</b> Phase III randomized trial of maintenance cabozantinib and avelumab vs maintenance avelumab after first-line platinum-based chemotherapy in patients with metastatic urothelial cancer Current Accrual: <b>0 Canadian Patients/654 (total accrual to date is 25)</b> <b>GCC1 (S1823):</b> A Prospective Observational Cohort Study to Assess miRNA 371 for Outcome Prediction in Patients with Newly Diagnosed Germ Cell Tumours Current Accrual: <b>130 Canadian Patients/956 (total accrual to date is 697)</b> <b>IND.234:</b> Prostate Cancer Biomarker Enrichment and Treatment Selection (PC_BETS) Study - Master Screening Protocol Current Accrual: <b>184 Canadian Patients/500 (521 screened)</b> <b>PR.19:</b> A Randomized Phase II Trial Evaluating Treatment Outcome, Acute and Long-term toxicity of High Dose Rate Brachytherapy (HDRB) and Low Dose Rate Brachytherapy (LDRB) as Monotherapy in Localized Prostate Cancer. Current Accrual: <b>222 Canadian Patients/335</b> <b>PR.20:</b> A Randomized Phase III Study of Local Ablative Therapy for Hormone Sensitive Oligometastatic Prostate Cancer (PLATON) Current Accrual: <b>286 Canadian Patients/410</b> <b>PR.21 PLUDO (Prostate Lutetium/Docetaxel):</b> A Randomized Phase II Study of 177Lu-PSMA-617 vs Docetaxel in Patients with Metastatic Castration-Resistant Prostate Cancer and PSMA-Positive Disease Current Accrual: <b>119 Canadian Patients/200 (135 screened)</b> <b>PR.22:</b> Darolutamide Augments Standard Therapy for Localized High-Risk Cancer of the Prostate (DASL-HiCaP) Current Accrual: <b>267 Canadian Patients/1100 (total accrual to date is 967)</b>	<b>W. Parulekar</b>
<b>1:00 pm</b>	<b>Closing Remarks</b>	<b>S. Hotte</b>



## Early Closure to Accrual

**BL.13:** A Randomized Phase II Trial Assessing Trimodality Therapy With Or Without Adjuvant Durvalumab To Treat Patients With Muscle-Invasive Bladder Cancer

**BL.13F:** Electronic 'Real-Time' Patient Self-Reporting of Immunotherapy Symptomatic Adverse Events using the SYMPTOM-IQ Tool on the uMotif Mobile Health Application (APP): A Prospective Feasibility Sub-Study of BL13 [e-PRISM]

**PNC.1 InPACT:** International Penile Advanced Cancer Trial

## Ongoing Trials: Closed to Accrual

**BLC.1/SWOG S1011:** Phase III Surgical Trial to Evaluate the Benefit of Standard versus an Extended Pelvic Lymphadenectomy Performed at the Time Of Radical Cystectomy For Muscle Invasive Urothelial Cancer

**BLC4/SWOG S1605:** Phase II Trial of Atezolizumab in BCG-Unresponsive Non-muscle Invasive Bladder Cancer

**PR13:** RADICALS: Radiotherapy and Androgen Deprivation In Combination After Local Surgery.

**PR17/ ANZUP 1304:** Randomised Phase III Trial of Enzalutamide in First Line Androgen Deprivation Therapy for Metastatic

**REC4/ECOG-ACRIN EA8143:** A Phase 3 Randomized Study Comparing Perioperative Nivolumab vs. Observation in Patients with Renal Cell Carcinoma Undergoing Nephrectomy (PROSPER RCC)



## Publications 2022/2023:

### 2023

#### IND234 (Abstract)

Prospective ctDNA genotyping for treatment selection in metastatic castration-resistant prostate cancer (mCRPC): The Canadian Cancer Trials Group phase II PC-BETS umbrella study. Kwan EM, Rushton MK, Tu W, Hotte SJ, Mukherjee SD, Ong M, Kolinsky MP, Hamilou Z, Winquist E, Ferrario C, Macfarlane RJ, Saad F, Salim M, Jiang DM, Tu D, Hutchenreuther J, Annala M, Seymour L, Chi KN, Wyatt AW. J Clin Oncol 41[6\_suppl], 218. 2023. Wolters Kluwer. 2-16-2023.

### 2022

Considerations on Integrating Prostate-Specific Membrane Antigen Positron Emission Tomography Imaging Into Clinical Prostate Cancer Trials by National Clinical Trials Network Cooperative Groups.

Schöder H, Hope TA, Knopp M, Kelly WK, Michalski JM, Lerner SP, Tawab-Amiri A, Mann BS, Lin DW, Yu EY, Chen RC, Beach GC, Reeves SA, Shankar LK.

J Clin Oncol 40: 1500-5, 2022.

DOI: [10.1200/JCO.21.02440](https://doi.org/10.1200/JCO.21.02440)

PMID: 35015566 PMCID: PMC9851697

#### REC.4 (Abstract)

LBA67 Phase III randomized study comparing perioperative nivolumab (nivo) versus observation in patients (Pts) with renal cell carcinoma (RCC) undergoing nephrectomy (PROSPER, ECOG-ACRIN EA8143), a National Clinical Trials Network trial.

Allaf M, Kim SE, Harshman LC, McDermott DF, Master VA, Signoretti S, Cole S, Moon H, Adra N, Singer EA, Gills J, Choueiri TK, Leibovich B, Michaelson MD, Shuch B, Lara PN, Heng DYC, Kapoor A, Carducci MA, Haas NB.

Ann Oncol 33, S1432-S1433. 2022.

DOI: <https://doi.org/10.1016/j.annonc.2022.08.072>

#### PR.13

RADICALS-HD: Reflections before the Results are Known.

Parker CC, Clarke NW, Catton C, Kynaston H, Cook A, Cross W, Davidson C, Goldstein C, Logue J, Maniatis C, Petersen PM, Neville P, Payne H, Persad R, Pugh C, Stirling A, Saad F, Parulekar WR, Parmar MKB, Sydes MR. Clin Oncol 34: 593-7, 2022.

DOI: <https://doi.org/10.1016/j.clon.2022.06.004>

#### PR.13 (Abstract)

LBA9 Duration of androgen deprivation therapy (ADT) with post-operative radiotherapy (RT) for prostate cancer: First results of the RADICALS-HD trial (ISRCTN40814031).

Parker CC, Clarke N, Cook A, Catton C, Cross WR, Kynaston H, Logue J, Petersen PM, Neville P, Persad R, Payne H, Saad F, Stirling A, Parulekar WR, Parmar MK, Sydes MR.

Ann Oncol 33, S1427. 2022.

DOI: <https://doi.org/10.1016/j.annonc.2022.08.064>

#### PR.17

Quality of Life in Men With Prostate Cancer Randomly Allocated to Receive Docetaxel or Abiraterone in the STAMPEDE Trial.

Rush HL, Murphy L, Morgans AK, Clarke NW, Cook AD, Attard G, Macnair A, Dearnaley DP, Parker CC, Russell JM, Gillessen S, Matheson D, Millman R, Brawley CD, Pugh C, Tanguay JS, Jones RJ, Wagstaff J, Rudman S, O'Sullivan JM, Gale J, Birtle A, Protheroe A, Gray E, Perna C, Tolan S, McPhail N, Malik ZI, Vengalil S, Fackrell D, Hoskin P, Sydes MR, Chowdhury S, Gilbert DC, Parmar MKB, James ND, Langley RE.

J Clin Oncol 40: 825-36, 2022.

DOI: [10.1200/JCO.21.00728](https://doi.org/10.1200/JCO.21.00728)

PMID: 34757812 PMCID: PMC7612717

#### PR.21 (Abstract)

Assessing the Impact of Dosimetry Method on Healthy Organ and Lesion Absorbed Dose Estimates for <sup>177</sup>Lu-PSMA-617 Therapy of Prostate Cancer: Early Experience from the Canadian Cancer Trials Group PR21 Trial (NCT 04663997).

Brosch-Lenz J, Hou X, Bloise I, Colpo N, Parulekar WR, Dellar C, Saad F, Chi K, Wilson D, Benard F, Rahmim A, Uribe C. European Journal of Nuclear Medicine and Molecular Imaging 49[Suppl 1], S394-S395. 2022.

Poster Presentation at EANM, Abstract EPS-213, October 15-19, 2022, Barcelona

#### PR.21 (Abstract)

Calibration Procedures for Multi-Center Dosimetry Studies with <sup>177</sup>-Lu Radiopharmaceuticals: Early Experience



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PR.21 Trial (NCT 04663997).

Uribe C, Colpo N, Broch-Lenz J, Dellar C, Parulekar W, Saad F, Chi K, Zukotynski K, Beauregard J, Benard F. European Journal of Nuclear Medicine and Molecular Imaging 49[Suppl 1], S186-S187. 2022.

Oral presentation, October 18, 2022, Abstract OP-563, EANM 2022, October 15-19, 2022, Barcelona

PR.22 (Abstract)

DASL-HiCaP: Darolutamide augments standard therapy for localized very high-risk cancer of the prostate (ANZUP1801). a randomized phase 3 double blind, placebo-controlled trial of adding darolutamide to androgen deprivation therapy and definitive or salvage radiation.

McBride SM, Niazi T, Williams S, Davis ID, Stockler M, Martin AJ, Bracken K, Roncolato FT, Horvath L, Sengupta S, Martin J, Lim T, Hughes S, McDermott RS, Catto JWF, Kelly PJ, Parulekar WR, Morgan SC, Rendon RA, Sweeney C.

Poster presentation, 2022 ASCO Genitourinary Cancers Symposium, San Francisco, CA. 2022. 2-17-2022.



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