

GENITOURINARY

SATURDAY APRIL 30TH, 2022, 9:30AM – 12:00 PM

CHAIRS: SEBASTIEN HOTTE, TAMIM NIAZI, AND WASSIM KASSOUF
 SENIOR INVESTIGATOR: 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

9:30 am	Main Meeting – Welcome	W. Parulekar & S. Hotte
9:35 am	New Trial Proposals	
	OPTIMUM Study Optimization of Prostate Biopsy - Micro-Ultrasound versus MRI (OPTIMUM study)	L. Klotz
	Lurbinectedin and Immune Checkpoint Inhibition in GU Malignancies with Neuroendocrine Features: a Multicenter, Phase II Trial	D. Jiang
	Docetaxel +/- carboplatin in mCRPC patients with DNA damage repair gene alterations	M. Kolinsky
	PAPMET2 (S2200) First line Cabozantinib vs Cabozantinib+ Atezolizumab in metastatic papillary RCC	W. Parulekar
	ASCENDE-SBRT 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	A. Loblaw

- 10:10am Approved: Pending Activation**
- Niraparib as Layered with Metastases Directed Therapy for Oligo-persistent High-volume Metastatic Hormone-Sensitive Prostate Cancer patients treated with ADT+ ARAT: a phase 2 multi-centric randomized trial **T. Niazi & S. Hotte**
- MAIN-CAV (A032001)** Phase III randomized trial of maintenance cabozantinib and avelumab vs maintenance avelumab after first-line platinum-based chemotherapy in patients with metastatic urothelial cancer **S. Sridhar**
- 10:20am Ongoing Trials: Open to Accrual** **W. Parulekar**
- 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]
- GCC1 (S1823)** A Prospective Observational Cohort Study to Assess miRNA 371 for Outcome Prediction in Patients with Newly Diagnosed Germ Cell Tumours
- IND.234:** Prostate Cancer Biomarker Enrichment and Treatment Selection (PC_BETS) Study - Master Screening Protocol
- PM.1:** Canadian Profiling and Targeted agent Utilization tRial (CAPTUR). A Phase II Basket Trial.
- PNC.1 InPACT:** International Penile Advanced Cancer Trial
- PR.19:** 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.
- PR.20:** A Randomized Phase III Study of Local Ablative Therapy for Hormone Sensitive Oligometastatic Prostate Cancer (PLATON)
- PR.21 PLUDO (Prostate Lutetium/Docetaxel):** A Randomized Phase II Study of 177Lu-PSMA-617 vs Docetaxel in Patients with Metastatic Castration-Resistant Prostate Cancer and PSMA-Positive Disease
- PR.22:** Darolutamide Augments Standard Therapy for Localized High-Risk Cancer of the Prostate (DSAL-HiCaP)
- 10:30 am Ongoing Trials: Closed**
- 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
- PR17/ ANZUP 1304** Randomised Phase III Trial of Enzalutamide in First Line Androgen Deprivation Therapy for Metastatic

REC3/SWOG S1500 A Randomized, Phase II Efficacy Assessment of Multiple MET Kinase Inhibitors (Cabozantinib [NSC #761968], Crizotinib [NSC #749005], Savolitinib [NSC #785348], and Sunitinib [NSC #736511]) in Metastatic Papillary Renal Carcinoma (PAPMET)

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

10:35am CCS Grant and Strategic Planning

W. Parulekar & S.Hotte

10:50am – 11:00am

Bio Break

11:00am – 11:40am: Guest speaker

Implementing MAMS Platform Protocols: Lessons From STAMPEDE
And Other Trials

M. Sydes

11:40am - 11:55am: Q&A

11:55am: Closing remarks

W. Parulekar & S.Hotte

Publications 2021/2022:

PR.7:

Hamilton RJ, Ding K, Crook JM, O'Callaghan CJ, Higano CS, Dearnaley DP, Horwitz EM, Goldenberg SL, Gospodarowicz MK, Klotz L. The Association Between Statin Use and Outcomes in Patients Initiating Androgen Deprivation Therapy. *European Urology* 79: 446-52, 2021.

PR.7:

Palmer MJ, Richardson H, Tu D, Brundage M. Factors predicting missing instruments in three cancer randomized clinical trials (ONLINE). *Qual Life Res* 2021.

PR.17:

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. Quality of Life in Men With Prostate Cancer Randomly Allocated to Receive Docetaxel or Abiraterone in the STAMPEDE Trial (ONLINE). *J Clin Oncol* 2021.

PR.17:

Sweeney CJ, Martin AJ, Stockler MR, Begbie S, Chi KN, Chowdhury S, Coskinas X, Frydenberg M, Hague WE, Horvath LG, Joshua AM, Lawrence NJ, Marx GM, McCaffrey J, McDermott R, McJannett M, North SA, Parnis F, Parulekar W, Pook DW, Reaume MN, Sandhu SK, Tan A, Tan TH, Thomson A, Tu E, Vera-Badillo F, Williams SG, Yip S, Zhang AY, Zielinski RR, Davis ID. Overall Survival of Men with Metachronous Metastatic Hormone-sensitive Prostate Cancer Treated with Enzalutamide and Androgen Deprivation Therapy. *European Urology* 80: 275-9, 2021.

PR.22 (Abstract):

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. 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. 2022. 2-17-2022.

REC.3 (Abstract):

Pal SK, Tangen C, Thompson IM, Haas NB, George DJ, Heng DYC, Shuch BM, Stein MN, Tretiakova MS, Humphrey P, Adeniran A, Narayan V, Bjarnason GA, Vaishampayan UN, Alva AS, Zhang T, Cole SW, Plets M, Wright J, Lara PLN. Sunitinib versus cabozantinib, crizotinib or savolitinib in metastatic papillary renal cell carcinoma (pRCC): Results from the randomized phase II SWOG 1500 study. *J Clin Oncol* 39[suppl 6; abstr 270]. 2021.

REC.3:

Pal SK, Tangen C, Thompson IM, Balzer-Haas N, George DJ, Heng DYC, Shuch B, Stein M, Tretiakova M, Humphrey P, Adeniran A, Narayan V, Bjarnason GA, Vaishampayan U, Alva A, Zhang T, Cole S, Plets M, Wright J, Lara PN. A comparison of sunitinib with cabozantinib, crizotinib, and savolitinib for treatment of advanced papillary renal cell carcinoma: a randomised, open-label, phase 2 trial. *The Lancet* 397: 695-703, 2021.

REC.4 (Abstract):

Allaf ME, Kim SE, Master VA, McDermott DF, Signoretti S, Cella D, Gupta RT, Cole S, Shuch BM, Lara PLN, Kapoor A, Chin Heng DY, Leibovich BC, Michaelson MD, Choueiri TK, Jewett MAS, Maskens D, Harshman LC, Carducci MA, Haas NB. PROSPER: Phase III Randomized Study Comparing PERioperative nivolumab versus observation in patients with renal cell carcinoma (RCC) undergoing nephrectomy (ECOG-ACRIN EA8143). *J Clin Oncol* 39[suppl 15; abstr TSP4596]. 2021.