CLINICAL TRIALS

Open clinical uro-oncology trials in Canada

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BLADDER CANCER

A PHASE III STUDY OF IRESSA® IN COMBINATION WITH INTRAVESICAL BCG VERSUS INTRAVESICAL BCG ALONE IN HIGH RISK SUPERFICIAL TRANSITIONAL CELL CARCINOMA OF THE BLADDER

Trial ID: NCIC BL.11
Coordination: National Cancer Institute of Canada Clinical Trials Group (NCIC CTG)
Trial design: A phase III study comparing intravesical BCG with and without gefitinib, an oral EGFR TK inhibitor.
Patient population: High risk Ta, Tis or T1 superficial bladder cancer with complete transurethral resection of all visible bladder lesions within 21 to 60 days prior to randomization, and without other evidence of metastasis.
Sample size & primary endpoint: n = 166, time to treatment failure

RANDOMIZED STUDY OF LAROTAXEL + CISPLATIN (LC) VS. GEMCITABINE + CISPLATIN (GC) IN THE FIRST LINE TREATMENT OF LOCALLY ADVANCED/METASTATIC UROTHELIAL TRACT OR BLADDER CANCER

Trial ID: NCT00625664, EFC6668, XRP9881
Coordination: sanofi-aventis
Trial design: Randomized, open-label, multi-center study comparing the efficacy and safety of XRP9881 plus cisplatin to gemcitabine plus cisplatin.
Patient population: First line treatment of locally advanced/metastatic urothelial tract or bladder cancer.
Sample size & primary endpoint: n = 900, overall survival

A RANDOMIZED, PLACEBO-CONTROLLED PHASE II STUDY TO COMPARE THE EFFICACY AND SAFETY OF SU011248 PLUS BEST SUPPORTIVE CARE (BSC) VERSUS PLACEBO PLUS BSC IN PATIENTS WITH ADVANCED UROTHELIAL TRANSITIONAL CELL CARCINOMA WHO HAVE FAILED OR ARE INTOLERANT TO CISPLATIN CONTAINING CHEMOTHERAPY

Trial ID: SPRUCE
Coordination: Canadian Urologic Oncology Group (CUOG)
Trial design: A randomized phase II study comparing sunitinib to placebo.
Patient population: Recurrent or metastatic transitional cell carcinoma failed, intolerant of, or ineligible for first-line cisplatin-based combination chemotherapy.
Sample size & primary endpoint: n = 58, progression-free survival

A MULTI-INSTITUTIONAL PHASE II STUDY OF SINGLE AGENT ABI-007 AS SECOND LINE THERAPY IN PATIENTS WITH ADVANCED TRANSITIONAL CELL CARCINOMA OF THE UROTHELIUM

Trial ID: ABX207-GU07CA
Coordination: Abraxis Bioscience Inc
Trial design: A single-arm, 2-stage phase II trial to assess the antitumor activity of ABI-007.
Patient population: Metastatic urothelial cancer progressed after cisplatin-based chemotherapy
Sample size & primary endpoint: n = 22, objective response

PROSTATE ADENOCARCINOMA

LOCALIZED PROSTATE CANCER

Low Risk

A PHASE III STUDY OF ACTIVE SURVEILLANCE THERAPY AGAINST RADICAL TREATMENT IN PATIENTS DIAGNOSED WITH FAVORABLE RISK PROSTATE CANCER (START)

Trial ID: NCIC CTG PR11
Coordination: NCIC CTG
Trial design: A phase III study comparing radical prostatectomy or radical radiotherapy at the time of initial diagnosis to active surveillance and selective intervention based on pre-specified biochemical, histological or clinical criteria.
Patient population: Suitable candidates for radical prostatectomy or radiotherapy. No previous treatment for prostate cancer for greater than 6 months. Favorable risk as defined by the following: clinical stage T1b, T1c, T2a or T2b, surgical Gleason score <= 6, PSA <= 10.0 ng/ml.
Sample size & primary endpoint: n = 2130, disease specific survival

A PHASE III RANDOMIZED STUDY OF HYPOFRACTIONATED 3D-CRT/IMRT VERSUS CONVENTIONALLY FRACTIONATED 3D-CRT/IMRT IN PATIENTS WITH FAVORABLE-RISK PROSTATE CANCER

Trial ID: RTOG 0415
Coordination: Radiation Therapy Oncology Group (RTOG)
Trial design: A randomized phase III non-inferiority trial assessing hypofractionated radiation of 70 Gy in 28 fractions to the prostate versus standard fractionation of 73.8 Gy in 41 fractions.
Patient population: Low-risk localized prostate cancer.
Sample size & primary endpoint: n = 1067, disease-free survival

Intermediate Risk

PROSTATE FRACTIONATED IRRADIATION TRIAL (PROFIT)

Coordination: Ontario Clinical Oncology Group (OCOG)
Trial design: A phase III study assessing the relative efficacy of dose-escalated radiation therapy (78 Gy in 39 fractions) versus a hypofractionated course of radiation (6000 Gy in 20 fractions).
Patient population: Intermediate-risk prostate cancer.
Sample size & primary endpoint: n = 1204, biochemical (PSA) failure

High Risk

A PHASE III STUDY OF NEOADJUVANT DOCETAXEL AND ANDROGEN SUPPRESSION PLUS RADIATION THERAPY VERSUS ANDROGEN SUPPRESSION ALONE PLUS RADIATION THERAPY FOR HIGH-RISK LOCALIZED ADENOCARCINOMA OF THE PROSTATE (DART)

Trial ID: NCIC PR12
Coordination: NCIC CTG
Trial design: A randomized phase III relative efficacy assessment of 3 years of androgen suppression combined with radical external beam radiation therapy (70 Gy-73 Gy) plus or minus neoadjuvant docetaxel chemotherapy (four cycles, 75 mg/m^2 q21 days).
Patient population: High-risk prostate cancer.
Sample size & primary endpoint: n = 530, disease-free survival

RANDOMIZED PHASE III STUDY OF NEO-ADJUVANT DOCETAXEL AND ANDROGEN DEPRIVATION PRIOR TO RADICAL PROSTATECTOMY VERSUS IMMEDIATE RADICAL PROSTATECTOMY IN PATIENTS WITH HIGH-RISK, CLINICALLY LOCALIZED PROSTATE CANCER

Trial ID:	NCIC PRC3
Coordination:	Intergroup (Cancer and Leukemia Group B)
Trial design:	A phase III comparison of neoadjuvant chemohormonal therapy with goserelin or leuprolide for 18-24 weeks with docetaxel IV every 3 weeks for up to six courses followed by radical prostatectomy with staging pelvic lymphadenectomy versus radical prostatectomy with staging lymphadenectomy alone.
Patient population:	High-risk prostate cancer.
Sample size & primary endpoint:	n = 750, 3 year biochemical progression-free survival

A PHASE III PROTOCOL OF ANDROGEN SUPPRESSION (AS) AND 3DCRT/IMRT VS AS AND 3DCRT/IMRT FOLLOWED BY CHEMOTHERAPY WITH DOCETAXEL AND PREDNISONE FOR LOCALIZED, HIGH-RISK PROSTATE CANCER

Trial ID:	RTOG 0521
Coordination:	RTOG
Study type:	Cooperative group
Trial design:	A randomized phase III relative efficacy assessment of 2 years of androgen suppression combined with radical external beam radiation therapy (72 Gy-75.6 Gy) with or without adjuvant docetaxel chemotherapy (six cycles, 75 mg/m^2 q21 days).
Patient population:	High-risk prostate cancer.
Sample size & primary endpoint:	n = 600, overall survival

PHASE III, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO EVALUATE THE EFFICACY OF ZOMETA® FOR THE PREVENTION OF OSTEOPOROSIS AND ASSOCIATED FRACTURES IN PATIENTS RECEIVING RADIATION THERAPY AND LONG TERM LHRH AGONISTS FOR HIGH-GRADE AND/OR LOCALLY ADVANCED PROSTATE CANCER

Trial ID:	RTOG 0518
Coordination:	RTOG
Trial design:	This randomized phase III trial is studying zoledronate versus placebo in the prevention of osteoporosis and bone fractures in patients with locally advanced nonmetastatic prostate cancer undergoing radiation therapy and hormone therapy.
Patient population:	Prostate cancer diagnosed within the past 6 months, clinical stage T3 OR Gleason score ≥ 8 OR PSA ≥ 30 ng/mL OR Gleason score ≥ 7 and PSA ≥ 15 ng/mL, baseline T score > -2.5 in both the L spine and the total hip by dual x-ray absorptiometry scan, and scheduled to receive a LHRH agonist for ≥ 1 year.
Sample size & primary endpoint:	n = 1272, freedom from any bone fracture

POST-RADICAL PROSTATECTOMY

RADIOTHERAPY AND ANDROGEN DEPRIVATION IN COMBINATION AFTER LOCAL SURGERY (RADICALS)

Trial ID: NCIC PR13
Coordination: Intergroup (MRC)
Trial design: A phase III study investigating immediate or deferred radiation with or without androgen deprivation therapy post radical prostatectomy.
Patient population: All men post radical prostatectomy.
Sample size & primary endpoint: n = 4000, disease-specific survival as primary endpoint

BIOCHEMICALLY RELAPSED PROSTATE CANCER

A PHASE II TRIAL OF SHORT-TERM ANDROGEN DEPRIVATION WITH PELVIC LYMPH NODE OR PROSTATE BED ONLY RADIOTHERAPY (SPORT) IN PROSTATE CANCER PATIENTS WITH A RISING PSA AFTER RADICAL PROSTATECTOMY

Trial ID: RTOG 0534
Coordination: RTOG
Trial design: Phase II comparing radiotherapy alone to radiotherapy with short-term androgen deprivation.
Patient population: Males who have undergone radical prostatectomy, followed by PSA rise to > 0.2 ng/ml.
Sample size & primary endpoint: n = 1764, 5-year freedom from progression

A RANDOMIZED COMPARISON OF IMMEDIATE VERSUS DEFERRED ANDROGEN DEPRIVATION THERAPY USING GOSERELIN FOR RECURRENT PROSTATE CANCER AFTER RADICAL RADIOTHERAPY

Trial ID: ELAAT
Coordination: OCOG
Trial design: A phase III trial comparing immediate to deferred androgen deprivation therapy.
Patient population: Patients who have undergone prior radical radiation for prostate cancer and are now experiencing a biochemical recurrence.
Sample size & primary endpoint: n = 1100, time to androgen independent disease

METASTATIC PROSTATE CANCER

PHASE III STUDY OF INTERMITTENT ANDROGEN DEPRIVATION IN PATIENTS WITH STAGE D2 PROSTATE CANCER

Trial ID: NCIC PR8, SWOG-9346
Coordination: Intergroup (SWOG)
Trial design/treatment: Randomized, multicenter study. Induction therapy: Patients receive combined androgen-deprivation (CAD) therapy comprising goserelin subcutaneously once a month and oral bicalutamide once daily for 8 courses (7 months). Patients are then randomized to 1 of 2 consolidation regimens. Arm I continuous CAD until disease progression. Arm II (intermittent CAD): Patients undergo observation only in the absence of rising prostate-specific antigen (PSA) or clinical symptoms of progressive disease. Patients with rising PSA or progressive disease begin CAD as in induction therapy.
Patient population: Histologically or cytologically confirmed adenocarcinoma of the prostate, clinical stage D2 as evidenced by soft tissue and/or bony metastases.
Sample size & primary endpoint: n = 1512, quality of life

A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE III STUDY OF EARLY VERSUS STANDARD ZOLEDRONIC ACID TO PREVENT SKELETAL RELATED EVENTS IN MEN WITH PROSTATE CANCER METASTATIC TO BONE

Trial ID: NCIC PRC2
Coordination: Intergroup (Cancer and Leukemia Group B)
Trial design: A phase III study comparing treatment with zoledronic acid at the time of initiation of androgen deprivation therapy for metastatic prostate cancer to treatment at time of progression to hormone-refractory disease.
Patient population: Metastatic prostate cancer with at least one bone metastasis by radiographic imaging receiving androgen deprivation therapy.
Sample size & primary endpoint: n = 680, time to first skeletal related event

HORMONE REFRACTORY PROSTATE CANCER

A PHASE III TRIAL OF ZD4054 (ENDOTHELIN A ANTAGONIST) IN NON-METASTATIC HORMONE RESISTANT PROSTATE CANCER

Trial ID: ENTHUSE M0/D4320C00015
Coordination: AstraZeneca
Trial design: Placebo controlled phase III trial to assess effectiveness of ZD4054 in HRPC
Patient population: HRPC with rising PSA after surgical or medical castration but no evidence of metastases
Sample size & primary endpoint: 1500, progression-free and overall survival

A PHASE III RANDOMIZED DOUBLE-BLIND STUDY TO ASSESS THE EFFICACY AND SAFETY OF 10 MG ZD4054 VERSUS PLACEBO IN PATIENTS WITH HORMONE-RESISTANT PROSTATE CANCER AND BONE METASTASES WHO ARE PAIN-FREE OR MILDLY SYMPTOMATIC

Trial ID: ENTHUSE M1/D4320C00014
Coordination: AstraZeneca
Trial design: Placebo controlled phase III trial
Patient population: HRPC with mildly/asymptomatic bone metastases, chemotherapy-naïve.
Sample size & primary endpoint: 580, overall survival

A MULTICENTRE, RANDOMIZED, DOUBLE-BLIND STUDY COMPARING THE EFFICACY AND SAFETY OF AFLIBERCEPT VERSUS PLACEBO EVERY 3 WEEKS IN PATIENTS TREATED WITH DOCETAXEL/PREDNISONE FOR METASTATIC ANDROGEN INDEPENDENT PROSTATE CANCER

Trial ID: VENICE/EFC6546
Coordination: sanofi-aventis
Trial design: A phase III study comparing the addition of aflibercept to standard docetaxel/prednisone.
Patient population: Metastatic hormone-refractory prostate cancer and no prior palliative chemotherapy.
Sample size & primary endpoint: n = 1200, overall survival

A RANDOMIZED, OPEN-LABEL MULTICENTRE STUDY OF XRP-6258 AT 25 MG/M² IN COMBINATION WITH PREDNISONE EVERY 3 WEEKS COMPARED TO MITOXANTRONE IN COMBINATION WITH PREDNISONE FOR THE TREATMENT OF HORMONE-REFRACTORY METASTATIC PROSTATE CANCER PREVIOUSLY TREATED WITH A TAXOTERE-CONTAINING REGIMEN

Coordination: sanofi-aventis
Trial design: Randomized phase III
Patient population: Hormone-refractory prostate cancer previously treated with docetaxel.
Sample size & primary endpoint: n = 720, overall survival

A PHASE III, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF ABIRATERONE ACETATE (CB7630) PLUS PREDNISONE IN PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER WHO HAVE FAILED DOCETAXEL-BASED CHEMOTHERAPY

Trial ID: COU-AA-301
Coordination: Cougar Biotechnology Inc.
Trial design: Randomized phase III
Patient population: A phase III study comparing abiraterone acetate 1000 mg PO daily plus prednisone 5 mg PO bid to placebo plus prednisone.
P**atient population:** Metastatic hormone-refractory prostate cancer previously treated with one or two chemotherapy regimens, one of which must have contained docetaxel.
Sample size & primary endpoint: n = 1158, overall survival

RENAL CELL CANCER

A RANDOMIZED, DOUBLE-BLIND PHASE III TRIAL OF ADJUVANT SUNITINIB VERSUS SORAFENIB VERSUS PLACEBO IN PATIENTS WITH RESECTED RENAL CELL CARCINOMA (ASSURE)

Trial ID: NCIC REC.2
Coordination: Intergroup (ECOG)
Trial design: A phase III surgical adjuvant study assessing the effectiveness of sunitinib or sorafenib compared to placebo.
Patient population: Resected renal cell carcinoma, T1b grade 3-4 or higher and/or N+.
Sample size & primary endpoint: n = 1332, overall survival

A RANDOMIZED TRIAL OF TEMSIROLIMUS AND SORAFENIB AS SECOND LINE THERAPY IN PATIENTS WITH ADVANCED RENAL CELL CARCINOMA WHO HAVE FAILED FIRST LINE SUNITINIB THERAPY

Trial ID: 3066K1-404-WW
Coordination: Wyeth
Trial design: An international, randomized, open label, multicenter phase III study assessing weekly temsirolimus versus sorafenib twice daily in the second line setting.
Patient population: Histologically confirmed metastatic renal cell carcinoma, progressive disease on sunitinib.
Sample size & primary endpoint: n = 440, progression-free survival and safety

TESTICULAR CANCER

PHASE II STUDY OF SUNITINIB IN MALE PATIENTS WITH RELAPSED OR CISPLATIN-REFRACTORY GERM CELL CANCER

Trial ID: CUOG-TE 05, NCT00371553
Coordination: CUOG, NCIC CTG, German Testicular Cancer Study Group
Trial design/treatment: Phase II, single arm. Sunitinib will be given at 50 mg once daily for 4 consecutive weeks followed by a 2-week rest period to comprise a complete cycle of 6 weeks.
Patient population: Histologically proven seminomatous or non-seminomatous germ cell cancer, patients with relapse within 8 weeks after at least two different cisplatin- based regimens or patients with disease progression or relapse after salvage high-dose chemotherapy or patients with disease progression during cisplatin-based and measurable disease.
Primary endpoint: response rate