CLINICAL TRIALS

Open clinical uro-oncology trials in Canada

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BLADDER CANCER

AN OPEN-LABEL, MULTICENTER, RANDOMIZED PHASE II STUDY EVALUATING THE SAFETY AND EFFICACY OF DOCETAXEL IN COMBINATION WITH RAMUCIRUMAB (IMC-1121B) DRUG PRODUCT OR IMC-18F1 OR WITHOUT INVESTIGATIONAL THERAPY AS SECOND-LINE THERAPY IN PATIENTS WITH LOCALLY ADVANCED OR METASTATIC TRANSITIONAL CELL CARCINOMA OF THE BLADDER, URETHRA, URETER, OR RENAL PELVIS FOLLOWING DISEASE PROGRESSION ON FIRST-LINE PLATINUM-BASED THERAPY

Trial ID: IMCL CP20-0902

Coordination: Imclone Systems

Trial design: Open-label phase II trial randomizing patients with metastatic urothelial carcinoma who have had disease progression on first-line platinum-based chemotherapy regimens to docetaxel alone or in combination with one of two anti-VEGFR monoclonal antibodies.

Patient population: Operable patients with stage T1 disease (T1G2 or T1G3) for whom radical cystectomy is being considered as the next conventional step in therapy by standard urologic guidelines.

Sample size & primary endpoint: n = 138, progression-free survival

PROSTATE ADENOCARCINOMA

LOCALIZED PROSTATE CANCER

Low Risk

A RANDOMIZED PHASE II TRIAL OF HYPOFRACTIONATED RADIOTHERAPY FOR FAVORABLE RISK PROSTATE CANCER

Trial ID: RTOG 0938

Coordination: RTOG

Trial design: A randomized phase II study assessing two hypo fractionated radiotherapy regimens in low risk prostate cancer.

Patient population: Histologically confirmed diagnosis of adenocarcinoma of the prostate within 180 days of randomization; Gleason scores 2-6; Clinical stage T1-2a; PSA < 10 ng/mL.

Sample size & primary endpoint: n = 174, EPIC Bowel score at 1 year after therapy

Intermediate Risk

A PHASE III PROSPECTIVE RANDOMIZED TRIAL OF DOSE-ESCALATED RADIOTHERAPY WITH OR WITHOUT SHORT TERM ANDROGEN DEPRIVATION THERAPY FOR PATIENTS WITH INTERMEDIATE RISK PROSTATE CANCER

Trial ID: RTOG 0815

Coordination: RTOG

Trial design: A randomized controlled trial to demonstrate an overall survival (OS) advantage for the addition of short term (6 months) ADT versus no additional ADT in the context of dose escalated RT for patients with intermediate risk prostate cancer.

Sample size & primary endpoint: n = 1520, overall survival

High Risk

PHASE III TRIAL OF DOSE ESCALATED RADIATION THERAPY AND STANDARD ANDROGEN DEPRIVATION THERAPY (ADT) WITH A GNRH AGONIST VS. DOSE ESCALATED RADIATION THERAPY AND ENHANCED ADT WITH A GNRH AGONIST AND TAK-700 FOR MEN WITH HIGH RISK PROSTATE CANCER

Trial ID: RTOG 1115
Coordination: RTOG
Trial design: To evaluate the difference in overall survival in men with clinically localized prostate cancer with unfavorable prognostic features between a) standard treatment (ADT + radiotherapy) and b) standard treatment with the addition of 24 months of TAK-700.
Patient population: Histologically confirmed diagnosis of adenocarcinoma of the prostate within 180 days prior to registration at high risk for recurrence.
Sample size & primary endpoint: n = 900, overall survival

PHASE III TRIAL OF DOSE ESCALATED RADIATION THERAPY AND STANDARD ANDROGEN DEPRIVATION THERAPY (ADT) WITH A GNRH AGONIST VERSUS DOSE ESCALATED RADIATION THERAPY AND ENHANCED ADT WITH A GNRH AGONIST AND TAK-700 FOR MEN WITH HIGH RISK PROSTATE CANCER

Trial ID: RTOG 1115
Coordination: RTOG
Trial design: A randomized phase III trial is studying the use of hormone therapy, including TAK-700, together with radiation therapy in treating patients with prostate cancer.
Patient population: Histologically confirmed diagnosis of adenocarcinoma of the prostate, high risk for recurrence as determined by one of the following combinations (risk group):
1. Gleason score (GS) ≥ 9, PSA ≤ 150 ng/mL, any T stage
2. GS ≥ 8, PSA < 20 ng/mL, T stage ≥ T2
3. GS ≥ 8, PSA ≥ 20-150 ng/mL, any T stage
4. GS ≥ 7, PSA ≥ 20-150 ng/mL, any T stage

Sample size & primary endpoint: n = 900, overall survival

ANDROGEN DEPRIVATION THERAPY AND HIGH DOSE RADIOTHERAPY WITH OR WITHOUT WHOLE-PELVIC RADIOTHERAPY IN UNFAVORABLE INTERMEDIATE OR FAVORABLE HIGH RISK PROSTATE CANCER: A PHASE III RANDOMIZED TRIAL

Trial ID: RTOG 0924
Coordination: RTOG
Trial design: Demonstrate that prophylactic neoadjuvant androgen deprivation therapy (NADT) and whole-pelvic radiation therapy (WPRT) will result in improvement in OS in patients with "unfavorable" intermediate risk or "favorable" high risk prostate cancer compared to NADT and high dose prostate and seminal vesicle (SV) radiation therapy (P + SV RT) using IMRT or EBRT with a HDR or a permanent prostate (radioactive seed) implant (PPI) boost in a phase III clinical trial.
Patient population: Patients who are most likely to benefit from ADT and WPRT, defined as: a) Having a significant risk of lymph node involvement (e.g. > 15%, based on the Roach formula) OR b) Being in one of the following risk groups: GS 7-10 + T1c-T2b (palpation) + PSA < 50 ng/mL (includes intermediate and high risk patients) GS 6 + T2c-T4 (palpation) or > 50% biopsies + PSA < 50 ng/mL GS 6 + T1c-T2b (palpation) + PSA > 20 ng/mL.
Sample size & primary endpoint: n = 2580 for a primary endpoint of overall 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 6 courses followed by RP with staging pelvic lymphadenectomy versus RP with staging lymphadenectomy alone.
Patient population: High-risk prostate cancer.
Sample size & primary endpoint: n = 750, 3 year biochemical progression-free survival

POST-RADICAL PROSTATECTOMY

RADICALS: RADIOTHERAPY AND ANDROGEN DEPRIVATION IN COMBINATION AFTER LOCAL SURGERY

Trial ID: NCIC PR13
Coordination: Intergroup (MRC)
Trial design: Phase III clinical trial with randomizations both for radiotherapy timing, and for hormone treatment duration.
Patient population: Men who have undergone radical prostatectomy for prostatic adenocarcinoma within 3 months, post-operative serum PSA less than 0.4 ng/ml. Uncertainty in the opinion of the physician and patient regarding the need for immediate post-operative RT.
Sample size & primary endpoint: n = 5100, disease free survival

BIOCHEMICALLY RELAPSED PROSTATE CANCER

A MULTICENTER CLINICAL STUDY OF THE SONABLATE® 500 (SB-500) FOR THE TREATMENT OF LOCALLY RECURRENT PROSTATE CANCER WITH HIFU

Trial ID: FSI-003
Coordination: Focus Surgery Inc.
Trial design: Single arm phase II.
Patient population: Men with locally recurrent prostate cancer following external beam irradiation.
Sample size & primary endpoint: n = 202, absence of biochemical failure and negative prostate biopsy rate at 12 months

A PROSPECTIVE PHASE II TRIAL OF TRANSPERINEAL ULTRASOUND-GUIDED BRACHYTHERAPY FOR LOCALLY RECURRENT PROSTATE ADENOCARCINOMA FOLLOWING EXTERNAL BEAM RADIOTHERAPY

Trial ID: RTOG 0526
Coordination: RTOG
Trial design: Single arm phase II.
Patient population: Men with biopsy-documented local recurrence > 30 months after external beam radiotherapy.
Sample size & primary endpoint: n = 96, late treatment-related GI/GU adverse events of brachytherapy

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

Trial ID: RTOG 0534
Coordination: RTOG
Trial design: Phase III 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

CASTRATE RESISTANT PROSTATE CANCER

A PHASE II STUDY OF PX-866 IN PATIENTS WITH RECURRENT OR METASTATIC CRPC

Trial ID: IND.205
Coordination: NCIC CTG
Trial design: A phase II trial of the oral PI-3K inhibitor, PX-866, in men with metastatic CRPC and no prior chemotherapy.
Sample size & primary endpoint: n = 40, lack of progression at 12 weeks

A RANDOMIZED PHASE III STUDY COMPARING STANDARD FIRST-LINE DOCETAXEL/PREDNISONE TO DOCETAXEL/PREDNISONE IN COMBINATION WITH CUSTIRSEN (OGX-011) IN MEN WITH METASTATIC CASTRATE RESISTANT PROSTATE CANCER

Trial ID: SYNERGY
Coordination: Teva/Oncogenex
Trial design: Randomized multicentre study of the addition of custirsen to docetaxel chemotherapy.
Patient population: Metastatic castration-resistant prostate cancer planned for treatment with docetaxel.
Sample size & primary endpoint: n = 800, overall survival

A RANDOMIZED, OPEN LABEL, MULTI-CENTER STUDY COMPARING CABAZITAXEL AT 25 MG/M2 AND AT 20 MG/M2 IN COMBINATION WITH PREDNISONE EVERY 3 WEEKS TO DOCETAXEL IN COMBINATION WITH PREDNISONE IN PATIENTS WITH METASTATIC CASTRATION RESISTANT PROSTATE CANCER NOT PRETREATED WITH CHEMOTHERAPY

Trial ID: NCT01308567
Coordination: sanofi
Trial design: Phase III
Patient population: Metastatic CRPC and not previously treated with chemotherapy.
Sample size & primary endpoint: n = 1170, overall survival

A PHASE II STUDY OF MAINTENANCE THERAPY WITH TEMSIROLIMUS IN ANDROGEN-INDEPENDENT PROSTATE CANCER AFTER FIRST LINE CHEMOTHERAPY WITH DOCETAXEL

Trial ID: OZM-018
Coordination: Sunnybrook Health Sciences Centre Odette Cancer Centre
Trial design: Single arm phase II.
Patient population: CRPC in remission after docetaxel.
Sample size & primary endpoint: n = 30, time to treatment failure

RANDOMIZED, OPEN LABEL MULTI-CENTER STUDY COMPARING CABAZITAXEL AT 20 MG/M2 AND AT 25 MG/M2 EVERY 3 WEEKS IN COMBINATION WITH PREDNISONE FOR THE TREATMENT OF METASTATIC CRPC PREVIOUSLY TREATED WITH A DOCETAXEL-CONTAINING REGIMEN

Trial ID: NCT01308580
Coordination: sanofi
Trial design: Phase III.
Patient population: Metastatic castration resistant previously treated with a docetaxel-containing regimen.
Sample size & primary endpoint: n = 1200, overall survival

RENAL CELL CANCER

A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE THERAPY FOR SUBJECTS WITH LOCALIZED OR LOCALLY ADVANCED RCC FOLLOWING NEPHRECTOMY III STUDY TO EVALUATE THE EFFICACY AND SAFETY OF PAZOPANIB AS ADJUVANT

Trial ID: PROTECT/VEG113387
Coordination: GlaxoSmithKline Inc.
Trial design: Double-blind placebo-controlled phase III.
Patient population: Resected predominantly clear cell renal cell cancer at higher risk of recurrence.
Sample size & primary endpoint: n = 1500, disease-free survival

IMMEDIATE SURGERY OR SURGERY AFTER SUNITINIB MALATE IN TREATING PATIENTS WITH METASTATIC KIDNEY CANCER

Trial ID: EORTC-30073/NCT01099423
Coordination: EORTC
Trial design: Phase III.
Patient population: Metastatic clear-cell renal cell carcinoma with a resectable asymptomatic in situ primary.
Sample size & primary endpoint: n = 458, progression-free survival

A RANDOMIZED PHASE II STUDY OF AFINITOR (RAD001) VS SUTENT (SUNITINIB) IN PATIENTS WITH METASTATIC NON-CLEAR CELL RENAL CELL CARCINOMA

Trial ID: ASPEN/NCT01108445
Coordination: Duke University
Trial design: Double-blind placebo-controlled phase III.
Patient population: Measurable metastatic predominantly non-clear cell renal cell cancer.
Sample size & primary endpoint: n = 108, progression-free survival

AN OPEN-LABEL, RANDOMIZED, MULTI-CENTER, PHASE III STUDY TO COMPARE THE SAFETY AND EFFICACY OF TKI258 VERSUS SORAFENIB IN PATIENTS WITH METASTATIC RENAL CELL CARCINOMA AFTER FAILURE OF ANTI-ANGIOGENIC (VEGF-TARGETED AND MTOR INHIBITOR) THERAPIES

Trial ID: NCT01223027
Coordination: Novartis
Trial design: Unblinded phase III.
Patient population: Metastatic renal cell carcinoma with clear cell carcinoma component and measurable disease who have received only one prior VEGF-targeted therapy and only one prior mTOR inhibitor therapy with progressive disease within 6 months of last therapy.
Sample size & primary endpoint: n = 550, progression-free survival