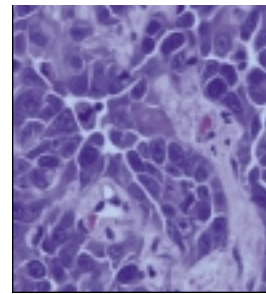


## CLINICAL RESEARCH PROTOCOLS FOR PROSTATE CANCER



# Clinical Research Protocols

### High Priority Trial

#### **NCI HIGH PRIORITY CLINICAL TRIAL — VA-CSP-407, NCI-T94-01310, PIVOT-1 Phase III Randomized Study of Prostatectomy vs Expectant Observation With Palliative Therapy for Stage I/II Prostate Cancer (PIVOT)**

Chairperson: Timothy James Wilt. Telephone: 612-725-2158. Lead organization: Veterans Affairs Cooperative Studies Program Coordinating Center - Perry Point. Age range: 75 and under.

### Phase III Trials

#### **CAN-NCIC-PR7, CAN-NCIC-JPR7, EU-99013** Phase III Randomized Study Comparing Intermittent Versus Continuous Androgen Suppression for Patients With Prostate Specific Antigen Progression in the Clinical Absence of Distant Metastases Following Radiotherapy for Prostate Cancer

Chairperson: Juanita M. Crook. Telephone: 416-946-2125. Lead organization: NCIC-Clinical Trials Group. Age range: 16 and over.

#### **SWOG-S9921** Phase III Randomized Study of Adjuvant Androgen Deprivation Therapy Plus Mitoxantrone and Prednisone Versus Androgen Deprivation Therapy Alone Following Radical Prostatectomy in Patients With High Risk Localized Prostate Cancer

Chairperson: L. Michael Glode. Telephone: 303-372-1550. Lead organization: Southwest Oncology Group. Age range: 30 to 85.

#### **CLB-9480, INT-0159** Phase III

Randomized Study of Low- Versus Intermediate- Versus High-Dose Suramin in Patients With Advanced Hormone-Refractory Adenocarcinoma of the Prostate

Chairperson: Richard L. Schilsky. Telephone: 773-834-3914. Lead organization: Cancer and Leukemia Group B. Age range: 18 and over.

#### **EORTC-22911** Phase III Randomized Study of Postoperative External Radiotherapy vs No Immediate Further Treatment in Patients With pT3 pN0 Prostatic Adenocarcinoma

Chairperson: Michel Bolla. Telephone: 33 476765506. Lead organization: EORTC Radiotherapy Group. Age range: 75 and under.

#### **MSKCC-98014, NCI-G98-1445** Phase III Randomized Study of the Effect of a Diet Low in Fat and High in Soy, Fruits, Vegetables, Green Tea, Vitamin E, and Fiber on PSA Levels in Patients With Prostate Cancer

Chairperson: Moshe Shike. Telephone: 212-639-7846. Lead organization: Memorial Sloan-Kettering Cancer Center. Age range: 18 and over.

#### **FRE-FNCLCC-GETUG-02, EU-98058** Phase III Randomized Study of Weekly Doxorubicin in Patients With Metastatic, Hormone-Refractory Prostate Cancer

Chairperson: Stephane Culine. Telephone: 33 4 67 61 3755. Lead organization: Federation Nationale des Centres de Lutte Contre le Cancer. Age range: over 18.

#### **EDAP-G980308, GUMC-99034** Phase III Study of the Ablath-

*This list of clinical research protocols relating to prostate cancer is compiled for your convenience.*

*For more information on these protocols, please call PDQ, a service of the National Cancer Institute, at 1-800-4-CANCER. The PDQ Web site is accessible at <http://cancer.net.nci.nih.gov/trialsrch.shtml>.*

*A searchable Web site developed by the National Library of Medicine is also available at <http://clinicaltrials.gov>.*

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erm High Intensity Focused Ultrasound Device in Patients With Stage I or II Prostate Cancer Following External Beam Radiotherapy

Chairperson: Linda J. Faupel. Telephone: 770-446-9950. Lead organization: EDAP Technomed, Inc. Age range: 50 and over.

## Phase II Trials

**NCI-00-C-0033** Phase II Randomized Study of Docetaxel With or Without Thalidomide in Patients With Androgen Independent Metastatic Prostate Cancer

Chairperson: William Dahut. Telephone: 301-496-4916. Lead organization: Division of Clinical Sciences. Age range: 18 and over.

**NCI-00-C-0154, NCI-894, NCI-NMOB-B00-021** Phase II Randomized Study of Radiotherapy With or Without Vaccine Containing Recombinant Vaccinia Prostate Specific Antigen (PSA) and rV-B7.1 Plus Recombinant Fowlpox PSA Vaccine in Patients With Localized Prostate Cancer

Chairperson: James Gulley. Telephone: 301-435-2956. Lead organization: National Cancer Institute Division of Clinical Sciences. Age range: 18 and over.

**UMASS-H-3745, NCI-V99-1546** Phase II Study of Docetaxel Plus Estramustine in Combination With Androgen Deprivation Therapy in Patients With PSA Elevation Following Radiotherapy or Radical Prostatectomy for Early Prostate Cancer

Chairperson: Mary Ellen Taplin. Telephone: 508-856-2114.

Lead organization: University of Massachusetts Memorial Medical Center. Age range: not specified.

**MCC-12219, NCI-G00-1863, MCC-IRB-5722** Phase II Study of Early Medical Adrenalectomy Using Hydrocortisone Combined With Aminoglutethimide or Ketoconazole in Patients With Localized Stage IV (D0.5) Adenocarcinoma of the Prostate

Chairperson: Randall P. Rago. Telephone: 813-972-8479. Lead organization: H. Lee Moffitt Cancer Center and Research Institute. Age range: not specified.

**RTOG-P-0019, RTOG-DEV-1064** Phase II Study of External Beam Radiotherapy Followed by Permanent Source Brachytherapy Using Interstitial Iodine I 125 Seeds in Patients With Intermediate Risk, Clinically Localized Adenocarcinoma of the Prostate

Chairperson: William Robert Lee. Telephone: 336-716-4464. Lead organization: Radiation Therapy Oncology Group. Age range: over 18.

**DFCI-94153, NCI-H97-1294** Phase II Study of Hyperthermia and Radiotherapy for Locally Advanced Adenocarcinoma of the Prostate

Chairperson: Mark Hurwitz. Telephone: 617-732-7936. Lead organization: Dana-Farber Cancer Institute. Age range: 18 and over.

**UCLA-990107702B, NCI-G99-1568, VCL-1102-202** Phase II Study of Neoadjuvant Leuvestin Followed by Retropubic Prostatectomy in Patients With Stage II or III Prostate Cancer

Chairperson: Arie Belldegrun. Telephone: 310-794-6584. Lead organization: Jonsson Comprehensive Cancer Center, UCLA. Age range: 18 and over.

**STBARN-IND-53879, NCI-V98-1509** Phase II Study of Paclitaxel Plus Estramustine in Patients With Metastatic Hormone Refractory Prostate Cancer

Chairperson: Stuart P. Leitner. Telephone: 973-533-5852. Lead organization: St. Barnabas Medical Center. Age range: not specified.

**CLB-9687** Phase II Study of the Role of Salvage Prostatectomy after Radiation Failure in Patients With Prostate Carcinoma

Chairperson: Gary D. Steinberg. Telephone: 773-702-3080. Lead organization: Cancer and Leukemia Group B. Age range: 75 and under.

**MSKCC-97007, NCI-G97-1232** Phase II/III Diagnostic Study of C11-Methionine and 2-F18-Fluoro-2-deoxy-D-Glucose (FDG) Positron Emission Tomography (PET) Imaging in Patients With Progressive Prostate Cancer.

Chairperson: Steven M. Larson. Telephone: 212-639-7373. Lead organization: Memorial Sloan-Kettering Cancer Center. Age range: not specified.

## Phase I Trials

**DFCI-98238, NCI-G00-1779, RP-DFCI-98238** Phase I Study of Estramustine, Docetaxel, and Carboplatin in Patients With Hormone Refractory Prostate Cancer

Chairperson: William Oh. Telephone: 617-632-3466. Lead organi-

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zation: Dana-Farber Cancer Institute. Age range: 18 to 85.

**UCLA-9909056-02, NCI-G00-1802** Phase I Study of Recombinant Prostate Specific Membrane Antigen (rPSMA) Pulsed Autologous Dendritic Cells (CaPVax) in Patients With Metastatic Hormone Refractory Prostate Cancer

Chairperson: Arie Belldegrun. Telephone: 310-794-6584. Lead organization: Jonsson Comprehensive Cancer Center, UCLA. Age range: 18 and over.

## Screening/Pilot Studies

**PLCO-1, NCI-P93-0050** A 16-Year Randomized Screening Study for Prostate, Lung, Colorectal, and Ovarian Cancer - PLCO Trial

Chairperson: John K. Gohagan. Telephone: 301-496-3982. Lead organization: National Cancer Institute Early Detection Branch. Age range: 55 to 74.

**E-3Z93, NCI-P95-0068** Randomized Pilot Study to Evaluate Educational Intervention and Behavioral Skills Training for Pain Control in Patients With Recurrent or Metastatic Breast or Prostate Cancer

Chairperson: Charles Cleeland. Telephone: 713-745-3470. Lead organization: Eastern Cooperative Oncology Group. Age range: 18 and over.