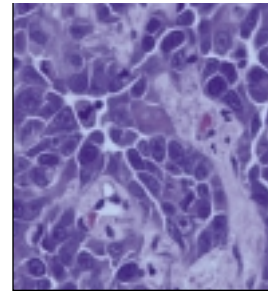


## CLINICAL RESEARCH PROTOCOLS FOR BLADDER CANCER



# Clinical Research Protocols

### Phase I

**MDA-DM-96172, NCI-T96-0073** Phase I Study of Adenovirus p53 in Patients With Locally Advanced and Metastatic Bladder Cancer (summary last modified 08/1999)

Chairperson: Lance C. Pagliaro. Telephone: 713-792-2830. Lead organization: University of Texas-MD Anderson Cancer Center. Age range: 18 and over.

**UCCRC-8270, NCI-G97-1156** Phase I Study of Concomitant Chemoradiotherapy With Vinorelbine and Paclitaxel in Patients With Advanced Pelvic Malignancies (summary last modified 03/1998)

Chairperson: Gini F. Fleming. Telephone: 312-702-6712. Lead organization: University of Chicago Cancer Research Center. Age range: over 18.

**MSKCC-97114, NCI-G98-1438** Phase I Study of Gemcitabine, Doxorubicin, and Paclitaxel Plus Carboplatin in Patients With Metastatic or Locally Advanced Transitional Cell Carcinoma of the Urothelium and Impaired Renal Function (summary last modified 09/1998)

Chairperson: Dean F. Bajorin. Telephone: 212-639-6708. Lead organization: Memorial Sloan-Kettering Cancer Center. Age range: 18 and over.

**NCI-94-C-0098A, NCI-T93-0182N** Phase I Study of Intravesical Suramin for Superficial Transitional Cell Carcinoma of the Bladder (summary last modified 11/1996)

Chairperson: McClellan M. Walther. Telephone: 301-402-2251.

Lead organization: Division of Clinical Sciences. Age range: 18 and over.

**MSKCC-97106, NCI-G97-1358** Phase I Study of Sequential Gemcitabine, Doxorubicin, Then Paclitaxel Plus Cisplatin Adjuvant Chemotherapy Following Complete Resection of Locally Advanced Transitional Cell Carcinoma of the Urothelium (summary last modified 12/1999)

Chairperson: Dean F. Bajorin. Telephone: 212-639-6708. Lead organization: Memorial Sloan-Kettering Cancer Center. Age range: 18 and over.

### Phase I/II

**WVU-13707-OSP-97-092, NCI-V97-1114** Phase I/II Study of Intravesical Paclitaxel (Taxol) for the Treatment of Superficial Bladder Cancer (summary last modified 01/1998)

Chairperson: Donald L. Lamm. Telephone: 304-293-2706. Lead organization: West Virginia University Hospitals. Age range: 18 and over.

**RTOG-9906, RTOG-DEV-14321** Phase I/II Study of Radiotherapy With Concurrent Paclitaxel and Cisplatin Followed By Selective Bladder Preservation or Radical Cystectomy and Adjuvant Chemotherapy in Patients With Stage II or III Muscle Invasive Carcinoma of the Bladder Treated With Transurethral Tumor Resection (summary last modified 02/2000)

Chairperson: Donald S. Kaufman. Telephone: 617-726-8689. Lead organization: Radiation Ther-

*This list of clinical research protocols relating to bladder 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.*

*A searchable PDQ Web site is also accessible at <http://cancernet.nci.nih.gov/trialsrch.shtml>*

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apy Oncology Group. Age range: not specified.

**MSKCC-97095, NCI-G97-1339**

Phase I/II Study of Sequential Doxorubicin/Gemcitabine and Ifosfamide, Paclitaxel, and Cisplatin Chemotherapy for Metastatic or Locally Advanced Transitional Cell Carcinoma of the Urothelium (summary last modified 12/1997)

Chairperson: Dean F. Bajorin. Telephone: 212-639-6708. Lead organization: Memorial Sloan-Kettering Cancer Center. Age range: 18 and over.

## Phase II

**ANTHRA-A9701/ID97-038,**

**MDA-ID-97038** Phase II Randomized Study of Peri-Operative Intravesical AD 32 Alone or Supplemented With BCG in Patients With Newly Diagnosed or Recurrent Superficial Bladder Cancer (summary last modified 11/1999)

Chairperson: Colin P.N. Dinney. Telephone: 713-792-3250. Lead organization: Anthra Pharmaceuticals, Inc. Age range: 18 and over.

**EORTC-22971** Phase II Study of Accelerated External Radiotherapy With Concurrent Fluorouracil and Cisplatin Following Transurethral Resection in Patients With Stage II or III Muscle Invasive Transitional Cell Carcinoma of the Bladder (summary last modified 12/1998)

Chairperson: Michel Bolla. Telephone: 33-476765506 (France). Lead organization: EORTC Radiotherapy Cooperative Group. Age range: under 76.

**BRI-BL-2** Phase II Study of Antineoplastons A10 and AS2-1 in Patients With Stage IV Bladder Carcinoma (Summary last modified 10/1998)

Chairperson: Stanislaw R. Burzynski. Telephone: 713-335-5625. Lead organization: Burzynski Research Institute. Age range: 18 and over.

**RPCI-DS-99-07, NCI-G99-1605**

Phase II Study of BCG Plus Interferon alfa 2b in Patients With Superficial Bladder Cancer (summary last modified 12/1999)

Chairperson: David A. Corral. Telephone: 716-845-3389. Lead organization: Roswell Park Cancer Institute. Age range: 18 and over.

**MSKCC-95031, NCI-V95-0743**

Phase II Study of CDDP/IFF/TAX in Advanced Urothelial Tumors (summary last modified 06/1998)

Chairperson: Dean F. Bajorin. Telephone: 212-639-6708. Lead organization: Memorial Sloan-Kettering Cancer Center. Age range: 18 and over.

**MRC-BA10, EU-97029** Phase II Study of Continuous Fluorouracil in Patients With Recurrent Locally Advanced or Metastatic Transitional Cell Urinary Tract Carcinoma (summary last modified 02/1998)

Chairperson: Peter G. Harper. Telephone: 44-171-9-55-50-00 (United Kingdom). Lead organization: Medical Research Council Clinical Trials Unit. Age range: not specified.

**E-2899** Phase II Study of Docetaxel and Gemcitabine in Patients With Progressive Regional or Metastatic Carcinoma of the

Urothelium (summary last modified 03/2000)

Chairperson: Robert Dreicer. Telephone: 216-445-4623. Lead organization: Eastern Cooperative Oncology Group. Age range: 18 and over.

**UCCRC-10021, NCI-G00-1733**

Phase II Study of Docetaxel and Methotrexate Followed By Gemcitabine and Cisplatin in Patients With Stage IV Locally Advanced or Metastatic Transitional Cell Carcinoma of the Urothelium (summary last modified 04/2000)

Chairperson: Walter M. Stadler. Telephone: 773-702-4400. Lead organization: University of Chicago Cancer Research Center. Age range: 18 and over.

**FHCRC-1365.00, NCI-G99-162**

Phase II Study of Interleukin-11 With Filgrastim (G-CSF) in the Mobilization of Peripheral Blood Stem Cells in Patients With Non-Hodgkin's Lymphoma, Hodgkin's Disease, Breast Cancer, or Other Solid Tumors (summary last modified 04/2000)

Chairperson: Leona Holmberg. Telephone: 206-667-6447. Lead organization: Fred Hutchinson Cancer Research Center. Age range: 70 and under.

**E-3897** Phase II Study of Intravesical AD 32 in Patients With Recurrent or Refractory Papillary Transitional Cell Carcinoma and/or Carcinoma In Situ of the Bladder (summary last modified 05/2000)

Chairperson: Jeffrey Mark Ignatoff. Telephone: 847-475-8600. Lead organization: Eastern Cooperative Oncology Group. Age range: 18 and over.

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**MSKCC-96066, NCI-H97-1118** Phase II Study of Methotrexate/ Vinblastine/Doxorubicin/Cisplatin Following Transurethral Resection of Bladder-Confined Tumor in Stage II Transitional Cell Carcinoma of the Bladder (summary last modified 02/1997)

Chairperson: Dean F. Bajorin. Telephone: 212-639-6708. Lead organization: Memorial Sloan-Kettering Cancer Center. Age range: 18 and over.

**UCCRC-10020, NCI-T99-0009** Phase II Study of Oxaliplatin in Patients With Metastatic Urothelial Carcinoma (summary last modified 04/2000)

Chairperson: Walter M. Stadler. Telephone: 773-702-4400. Lead organization: University of Chicago Cancer Research Center. Age range: 18 and over.

**E-5899** Phase II Study of Paclitaxel and Gemcitabine in Patients With Advanced Transitional Cell Carcinoma of the Urothelium With Renal Insufficiency (summary last modified 05/2000)

Chairperson: Robert L. Comis. Telephone: 215-893-6440. Lead organization: Eastern Cooperative Oncology Group. Age range: 18 and over.

**E-3896** Phase II Study of Pirarixim in Refractory Urothelial Carcinoma (summary last modified 08/1998)

Chairperson: Bruce J. Roth. Telephone: 615-343-4070. Lead organization: Eastern Cooperative Oncology Group. Age range: 18 and over.

**CAN-NCIC-IND128, SPRI-CAN-NCIC-IND128** Phase II Study

of SCH 66336 in Patients With Previously Treated, Inoperable, Locally Advanced or Metastatic Transitional Cell Carcinoma of the Bladder (summary last modified 04/2000)

Chairperson: Malcolm J. Moore. Telephone: 416-946-2263. Lead organization: NCIC-Clinical Trials Group. Age range: 18 and over.

**EORTC-30971** Phase II Study of Thorough Transurethral Resection and Escalated Dose Methotrexate/ Vinblastine/Doxorubicin/Cisplatin (M-VAC) in Patients With Transitional Cell Carcinoma of the Bladder (summary last modified 12/1998)

Chairperson: Cora N. Sternberg. Telephone: 011-39-6-5240-6812 (Italy). Lead organization: EORTC Genito-Urinary Tract Cancer Cooperative Group. Age range: not specified.

### Phase III

**MDA-ID-95236, NCI-G99-1621** Phase III Randomized Chemoprevention Study of Fenretinide in Patients With Superficial Bladder Cancer (summary last modified 05/2000)

Chairperson: H. Barton Grossman. Telephone: 713-792-3250. Lead organization: University of Texas-MD Anderson Cancer Center. Age range: 18 and over.

**SWS-SAKK-06/98, EU-98075** Phase III Randomized Study Comparing Two BCG Strains in Patients With Ta or T1 Papillary Carcinoma of the Urinary Bladder or Carcinoma in Situ of the Uri-

nary Bladder (summary last modified 10/1999)

Chairperson: George N. Thalman. Telephone: 031-632-36-41 (Switzerland). Lead organization: Swiss Institute for Applied Cancer Research. Age range: 18 to 90.

**ANTHRA-A9601** Phase III Randomized Study of AD 32 Following Transurethral Resection in Patients With Newly Diagnosed or Recurrent Superficial Transitional Cell Carcinoma of the Bladder (summary last modified 02/2000)

Chairperson: Peter R. Carroll. Telephone: 415-476-1611. Lead organization: Anthra Pharmaceuticals, Inc. Age range: 18 and over.

**SWOG-9809** Phase III Randomized Study of Ciprofloxacin vs Cephalexin in Patients With Stage Ta Transitional Cell Carcinoma of the Bladder Treated With Transurethral Tumor Resection (summary last modified 04/2000)

Chairperson: David P. Wood. Telephone: 313-745-7381. Lead organization: Southwest Oncology Group. Age range: 18 and over.

**NCCTG-979252, NCI-P98-0138** Phase III Randomized Study of High Dose Multivitamins as Chemoprevention of Stage 0 and I Resected Transitional Cell Carcinoma of the Bladder (summary last modified 04/2000)

Chairperson: Michael L. Blute. Telephone: 507-284-3982. Lead organization: North Central Cancer Treatment Group. Age range: 18 and over.

**E-4897** Phase III Randomized Study of Methotrexate, Vinblastine,

Doxorubicin, and Cisplatin (M-VAC) Versus Carboplatin and Paclitaxel for the Treatment of Advanced Carcinoma of the Urothelium (summary last modified 01/1999)

Chairperson: Bruce J. Roth. Telephone: 615-343-4070. Lead organization: Eastern Cooperative Oncology Group. Age range: 18 and over.

**E-1897** Phase III Randomized Study of Methotrexate, Vinblastine, Doxorubicin, and Cisplatin Versus Paclitaxel and Carboplatin as Post-operative Adjuvant Therapy in Patients With Muscle-Invasive Transitional Cell Carcinoma of the Bladder at High Risk for Relapse (summary last modified 07/1999)

Chairperson: Bruce J. Roth. Telephone: 615-343-4070. Lead organization: Eastern Cooperative Oncology Group. Age range: any age.

**NYU-9852, NCI-G00-1715, LAC-USC-4B951** Phase III Randomized Study of Methotrexate, Vinblastine, Doxorubicin, and Cisplatin vs Observation Alone Based on p53 Gene Status in Patients With Organ Confined Transitional Cell Carcinoma of the Bladder Who Have Undergone Radical Cystectomy and Bilateral Pelvic Lymphadenectomy (summary last modified 04/2000)

Chairperson: Samir Taneja. Telephone: 212-263-6420. Lead organization: Kaplan Cancer Center. Age range: any age.

**MRC-BS06, EU-91019** Phase III Randomized Trial of Adjuvant Radical Radiotherapy vs Observation or Intravesical Chemotherapy With BCG or MITO Following

Endoscopic Resection of pT1 G3 Nx M0 Bladder Cancer (summary last modified 06/1995)

Chairperson: Stephen John Harland. Telephone: 171-3-80-9328 (United Kingdom). Lead organization: Medical Research Council Clinical Trials Unit. Age range: any age.

**EORTC-30962** Phase III Study of Long Term vs Short Term Maintenance With Intravesical BCG at Either Standard Dose or 1/3 Dose in Patients With Intermediate and High Risk Ta or T1 Papillary Carcinoma of the Urinary Bladder (summary last modified 01/1999)

Chairperson: Maurizio Brausi. Telephone: 39-2-2643-2483 (Italy). Lead organization: EORTC Genito-Urinary Tract Cancer Cooperative Group. Age range: 85 and under.

**Legend for Abbreviations:**

- ANTHRA = Anthra Pharmaceuticals, Inc
- BRI = Burzynski Research Institute
- CAN-NCIC = National Cancer Institute of Canada
- E = Eastern Cooperative Oncology Group
- EORTC = European Organization for Research on Treatment of Cancer
- EU = European Voluntary Protocol
- LAC-USC = University of Southern California
- MDA = MD Anderson Cancer Center
- MRC = UK Medical Research Council

- MSKCC = Memorial Sloan-Kettering Cancer Center
- NCCTG = North Central Cancer Treatment Group
- NCI = National Cancer Institute
- NYU = New York University Cancer Center
- RPCI = Roswell Park Cancer Institute
- RTOG = Radiation Therapy Oncology Group
- SPRI = Schering-Plough Research Institute
- SWOG = Southwest Oncology Group
- SWS-SAKK = Swiss Group for Clinical Cancer Research
- UCCRC = University of Chicago Cancer Research Center
- WVU = West Virginia University Hospitals