### **PUBLICATIONS**

W. Stewart Bundrick, Daniel J. Culkin, John A. Mata and Dennis D. Venable. Unresectable Calcified Bladder Tumor Bladder: Hemiacidrin Irrigation as an Adjunct to Resection. *J. Urol.*, 145:142, 1991

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W. Stewart Bundrick, Daniel J. Culkin, John A. Mata, Enrique Gonzales, Roger Zitman and Dennis D. Venable. Penile Malignant Melanoma in Association with Squamous Cell Carcinoma of the Penis.

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Anatomic, Functional and Pathologic changes from Internal Ureteral Stent Placement. *Urology*, 40:385, 1992

W. Stewart Bundrick, Daniel J. Culkin, Roger I. Zitman, John A. Mata, Dennis D. Venable. Evaluation of the Current Incidence of Nodal Metastasis from Prostate Cancer. *J. of Surg. Oncology*, *152:269-271*, *1993* 

W. Stewart Bundrick, Dennis D. Venable, Kevin Sittig, Edwin Dietch. Primary Scrotal Reconstruction in Fournier's Gangrene. *Infections in Urology, July 1994* 

Chris Petrus, W. Stewart Bundrick, Daniel J. Culkin, James E. Eastham

Spontaneous Drainage of an Appendiceal Abscess Into an Orthotopic Neobladder.

J. of Urology, 155:2028, June 1996

W. Stewart Bundrick, Robert P. Gibbons, Robert M. Weissman, Roy J. Correa. The Long-term Efficacy of Radical Prostatectomy in the Management of Clinically Localized Prostate Cancer. Submitted J. Urol Kubricht, W.S., III, Henderson, R.J., Bundrick, W.S., Jr.,

Venable, D.D., Eastham, J.H., Renal Cell Carcinoma in an Intrathoracic Kidney. Southern Medical Journal 92:628-629, 1999

#### **CLINICAL TRIALS**

AstraZeneca- Protocol Number 705IL/0023:0103. A randomized double-blind comparative trial of Bicalutamide (Casodex) versus placebo in patients with early prostate cancer. Open

AstraZeneca- Protocol Number 7054US/0007. A randomized trial with Bicalutamide (Casodex) 150mg Monotherapy in patients with hormone refractory prostate cancer. Closed

Alza- Protocol Number C-98-008. Reformulation of long acting Ditropan XL phase III study. Closed

Glaxo Wellcome Inc.- Protocol Number ARIA3001. A randomized double-blind, placebo controlled tow year parallel group of the efficacy and safety of GI198745 O.5 mg in the treatment and prevention of progression of benign prostatic hyperplasia. Closed

AstraZeneca- Protocol Number 7054US/0009. A randomized trial with Bicalutamide (Casodex) 150mg monotherapy in patients with prostate cancer to determine the reduction of incidence of high-grade prostatic intraepithelial neoplasia (HGPIN) prior to radical prostatectomy.

Closed

TAP Pharmaceutical Product Inc. - Protocol Number M99-051. A phase II randomized-discontinuation study of oral CEP-701 in prostate cancer patients who have failed first-line hormonal therapy. Closed

TAP Pharmaceutical Product Inc. - Protocol Number M99-121. A phase II, long-term, open-label extension study of oral CEP-701 in patients previously receiving CEP-701 for treatment of prostate cancer. Closed

Ortho-McNeil Pharmaceutical – Protocol CAPSS 101. A multicenter, double-blind study to compare the safety and efficacy of levofloxacin to that of Ciprofloxacin in the treatment of chronic prostatitis. Closed

#### **CLINICAL TRIALS**

FEI Technologies Protocol Number FEI-001.

The safety, local tolerability, pharmacokinetics, and risk/benefit of oxybutynin transvaginal rings (TVR) in women with a history of overactive bladder.

Closed

Ono Pharmaceuticals- Protocol Number AIO-8507L-US0104. A double-blind placebo-controlled, parallel-group safety and efficacy study evaluating three dose regimens of AIO-8507L, a selective alpha-adrenergic antagonist, in the treatment of benign prostatic hyperplasia.

Closed

Eli Lilly- Protocol Number F1J-MC-SBAV. Efficacy and safety of duloxetine compared with placebo in the relief of stress urinary incontinence.

Closed

Eli Lilly- Protocol Number F1J-MC-SBAW. Long-term monitoring of safety in subjects treated with duloxetine for stress urinary incontinence.

Open

Pharmacia & Upjohn- Protocol Number 583E-URO-0084-018. Pharmacokinetics and safety of tolterodine 2 and 4 mg once daily in children 11 to 15 years of age. An open, dose-escalation study in patients with overactive bladder.

Closed

Pharmacia & Upjohn- Protocol Number 583E-URO-0084-021. Long-term safety, tolerabilty and clinical efficacy of tolterodine prolonged release capsules in children 5 to 15 years of age. A phase III open-label, multinational 12 month study. Closed

Boehringer Ingelheim Pharmaceutical - Protocol Number 527.26. A two phase, double-blinded, randomized, parallel-group design, multicenter study of Flomax capsules, 0.4 mg versus placebo, in male patients with acute urinary retention related to benign prostatic hyperplasia.

Open

Sanofi-Synthelabo- Protocol EFC4428. A double-blind randomized-d parallel group study of Alfuzosin 10mg OD versus placebo in the management of acute urinary retention in patients with a first episode due to BPH.

Closed

### CLINICAL TRIALS CONT

Celsion Corporation- Protocol Number 3. A randomized study with microwave uroplasty and Proscar for the treatment of benign prostatic hyperplasia.

Closed

Abbott Laboratories- Protocol Number M00-211. A phase III, randomized, double-blind, placebo-controlled, safety and efficacy study of 10mg Atrasentan in men and metastatic,hormone-refractory prostate cancer.

Closed

Abbott Laboratories- Protocol Number M00-244. A phase III, randomized, double-blind, placebo-controlled, safety and efficacy study of 10mg Atrasentan in men with non-metastatic, hormone-refractory prostate cancer.

Open

Abbott Laboratories- Protocol Number M00-258. A phase III extension study to evaluate the safety of 10mg Atrasentan in men with hormone-refractory prostate cancer. Closed

Eli Lilly- Protocol Number F1J-MC-SBBL. Efficacy and safety of Duloxetine compared with placebo in subjects with symptoms of bladder overactivity due to pure detrusor instability or sensory urgency. Closed

Sepracor- Protocol Number 332-146. Double-blind, placebo and active controlled study of sustained release (S)-Oxybutynin in subjects with symptoms of overactive bladder of urgency, frequency and urinary incontinence.

Closed

Gtx Innovative Technologies- Protocol Number Gtx-006-211. A multicenter, phase Iib, four arm, dose finding, randomized, placebo-controlled study to determine the long term prostate cancer chemoprevention efficacy and safety of 20mg, 40mg & 60mg daily of Gtx-006 in men with High Grade Prostate Inraepithelial Neoplasia (PIN).

Closed

Pharmacia & Upjohn- Protocol Number 583E-URO-0581-001. Phase I/II, open label, dose-escalating pharmacokinetic, pharmacodynamic (urodynamic) and clinical effect, and safety study of tolterodine liquid in children with detrusor hyperreflexia 1 month to 4 years of age.

Closed

## CLINICAL TRIALS CONT

Pharmacia & Upjohn- Protocol Number 583E-URO-0581-002. Phase I/II, open label, dose-escalating pharmacokinetic, pharmacodynamic (urodynamic) and clinical effect, and safety study of tolterodine liquid in children with detrusor hyperreflexia 5 to 10 years of age. Closed

Pharmacia & Upjohn- Protocol Number 583E-URO-0581-003. Phase I/II, open label, dose-escalating pharmacokinetic, pharmacodynamic (urodynamic) and clinical effect, and safety study of tolterodine PR capsules in children with detrusor hyperreflexia 11 to 15 years of age. Closed

Pharmacia & Upjohn- Protocol Number 583E-URO-0581-006. An open-label, phase III, 12 month study of the long-term clinical efficacy, safety and tolerability of tolterodine oral solution and PR capsules in children with detrusor hyperreflexia ages 4 months to 16 years of age. Closed

Pharmacia & Upjohn- Protocol Number 583E-URO-0581-007. An open label, multicenter, multinational study to determine the efficacy and safety of tolterodine oral solution in children 5 to 10 years of age with symptoms of urge urinary incontinence suggestive of detrusor instability. Closed

Pharmacia & Upjohn- Protocol Number 583E-URO-0581-008. A phase III, randomized, double blind, multicenter and multinational study to determine the efficacy and safety of tolterodine prolonged release capsules in children 5 to 10 years of age with symptoms of urge urinary incontinence, suggestive of detrusor instability. Closed

Pharmacia & Upjohn- Protocol Number DETAPE-0581-009. A phase III, open label extension and long term safety study of tolterodine PR capsules in children 5 to 11 years of age with symptoms of urge urinary incontinence suggestive of detrusor instability. Closed

Novartis- Protocol Number CZOL446EUS24. An open label trial on the effect of I.V. Zometa 4mg on bone mineral density in hormone sensitive prostate cancer patients. Closed

## CLINICAL TRIALS CONT

Myriad Pharmaceuticals- Protocol Number MPR-7869-001. Phase Iib, multicenter, randomized, double blind, placebo-controlled trial to assess the safety and efficacy of MPC-7869 in delaying the systemic progression of prostate cancer in patients with intermediate to high risk of recurrence with rising PSA levels after prostatectomy and radiotherapy or radiotherapy alone for localized disease. Open

GTx Innovative Technologies- Protocol Number GTx-006-300. A phase II, four arm, dose finding, randomized, placebo-controlled study to determine the safety and efficacy of 20mg, 40mg and 60mg toremifene in the prevention of osteoporosis of androgen deprivation. Closed

Gtx Innovative Technologies- Protocol Number Gtx-006-400. A phase II, four arm, dose finding, randomized, placebo-controlled study to determine the safety and efficacy of 20mg, 40mg, and 60mg

toremifene in the treatment of osteoporosis of androgen deprivation. Closed

Sanofi-Synthelabo Inc.- Protocol Number L-8472 (ALF-ACUTE). A phase III. The efficacy, onset of effect, and safety of Alfuzosin once daily in the treatment of lower urinary tract symptoms of benign prostatic hyperplasia: A randomized, placebo-controlled trial using an acute international prostate score (ALF\_ACUTE). Closed

Pharmacia- Protocol Number 583E-URO-0084-037. A Phase III double-blind, placebo-controlled, randomized US study to evaluate the effect of Tolterodine Prolonged Release on nocturia in patients with symptoms of overactive bladder (OAB). Closed

Pfizer Inc- Protocol Number A1481137. A Phase IV multicenter, open-label, flexible dose escalation study to evaluate the correlation between event log parameters, Self Esteem/Overall Relationships, and Efficacy of Viagra (Sildenafil Citrate) in men with erectile dysfunction.

Closed

Kyowa Pharmaceutical Inc. - Protocol Number 7158-INT-001. Phase II. A 6 week, double-blind, placebo-controlled, randomized, parallel group, multicenter, multidose study of the efficacy and safety of KW-7158 in patients with overactive bladder symptoms of increased urinary frequency, urgency and urge incontinence. Closed

### CLINICAL TRIALS CONT

Celsion- Protocol Number 103-02-101, Phase I A dose escalation, Pharmacokinetics and Safety Study of Doxorubicin Encapsulated in Temperature Sensitive Lipsomes Released through Microwave Therapy in the treatment of Prostate Cancer.

Open

Indevus- Protocol Number IP631-005. A double-blind, placebo-controlled study of Urinary Frequency and Urgency using Trospium Chloride, 20mg Tablets, twice daily, for 12 weeks followed by a 6-month, open-label treatment phase in patients with overactive bladder. Closed

Ferring- Protocol Number FE200486CS14. An open label, randomized, multicenter, parallel group comparison of the efficacy and safety of Degarelix at two different dosing regimens in patients with prostate cancer dosed for thirteen 28-day cycles. Open

Ortho-McNeil- Protocol Number CAPSS-263. A double-blind, randomized, placebo-controlled trial of Elmiron (Pentosan Polysulfate Sodium) for the treatment of chronic non-bacterial prostatitis. Open

GlaxoSmithKline- Protocol ARI40006. A randomized, double-blind, placebo-controlled, parallel group study of the efficacy and safety of Dutasteride 0.5mg administered orally once daily for four years to reduce the risk of biopsy-detectable prostate cancer.

Open

McNeil- Protocol 14-101. A placebo-controlled study evaluating the safety and efficacy of Oxybutynin Chloride 3mg and 5mg in women with overactive bladder.

Open

Lilly- Protocol F1J-US-SBCD. Study of Duloxetine HCI in women of different demographic characteristics and co-morbidities with stress urinary incontinence: Evaluation of efficacy and safety. Open

GTx- Protocol G300203. A randomized, double-blind, placebocontrolled, multicenter efficacyand safety study of Toremifene Citrate for the prevention of bone fractures in men with prostate cancer on Androgen Deprivation Therapy. Open

Merck- Protocol 201. A double-blind, randomized, placebo-controlled, multicenter study to evaluate the effects of Rofecoxib in decreasing

the risk of prostate cancer. Open

# CLINICAL TRIALS CONT

Novartis- Protocol US05. A double-blind, placebo-controlled study of the effect of Zoledronic Acid on bone mineral density in men receiving Androgen Deprivation Therapy for prostate cancer.

Open