

RONALD F. TUTRONE, JR., M.D.

Chesapeake Urology Associates/ Partner
Chesapeake Urology Research Associates/ Medical Director
6535 North Charles Street PPN Suite 625
Towson, MD 21204

6820 Hospital Drive Suite 210
Baltimore, MD 21237

8322 Bellona Ave Suite 202
Towson, MD 21204

806 Landmark Drive Suite 118
Glen Burnie, MD 21061

PERSONAL

Date of Birth: November 27, 1961
Place of Birth: Brooklyn, NY

EDUCATION

9/79-5/83 College of the Holy Cross,
Worcester, MA
B.A. Chemistry

8/83-6/87 UMDNJ-Robert Wood Johnson Medical School,
Piscataway, NJ
Doctor of Medicine

GENERAL SURGERY

7/87-6/88 Kings County Hospital/SUNY-Downstate Medical Center
Brooklyn, NY
Internship

7/88- 6/89 Kings County Hospital/SUNY-Downstate Medical Center
Brooklyn, NY
Resident in General Surgery

RESIDENCY TRAINING

Harvard Program in Urology (Longwood Area)

7/89-9/93 Brigham and Women's Hospital, Beth Israel Hospital,
The Children's Hospital, Dana-Farber Cancer Institute,
West Roxbury Veteran's Hospital
Boston, MA

- Resident in Urological Surgery

7/90-6/91 Hartwell Harrison Urologic Research Laboratory
Harvard Medical School, Boston, MA

- Urologic Research Fellow

BOARD CERTIFICATION/ LICENSURE AND GENERAL CERTIFICATION

American Board of Urology

- Certified: March 24, 1995
- Re-Certified: November 2003
- Certificate #11119
- Surgical Laser (CO2, Nd-YAG,KTP and Pulsed Dye)
- PVP Green Light Laser
- DaVinci Robot Trained

HOSPITAL AFFILIATIONS

- Greater Baltimore Medical Center
- St. Joseph Medical Center
- Union Memorial Hospital

NOTEWORTHY HONORS AND AWARDS

- Baltimore Magazine, “Top Doc” 2000,2004,2008, 2010, 2011
- Resident Essay Contest, First Prize 1991
- Washington Post “Super Docs” 2012
AUA New England Section, Dixville Notch, NH
- Basic Science Research, Second Prize 1991
Annual Resident Research Competition
Harvard/Countway Urology Rounds
- Alpha Omega Alpha 1987
- Phi Beta Kappa 1983
- Cum Laude- Holy Cross 1983
- Dean’s List Four Consecutive Years 1979-1983
- Memorial Sloan-Kettering Cancer Center/
Roche Institute of Molecular Biology Research Scholarship 1982
- Memorial Sloan-Kettering Cancer Center/
Roche Institute of Molecular Biology Research Scholarship 1981

MEDICAL SOCIETIES

- American College of Surgeons, Fellow
- American Urological Association, Member
- Maryland Urological Association, Member

ACADEMIC APPOINTMENTS

Harvard Medical School, Clinical Fellow in Surgery	07/89-06/93
Union Hospital of Cecil County, Chief of Surgery	01/98-01/00
Eli Lilly Scientific Advisory Board for Duloxetine	10/02-01/04
GlaxoSmithKline National Advisory Board for Avodart	07/03-07/08
GBMC Foundation Board Member	01/04-01/06
Surgical Advisory Committee, GBMC	07/99-Present
Medical Director, Baltimore Lithotripsy Associates	01/00-Present
Chief of Urology-Greater Baltimore Medical Center	01/06-Present
GBMC Hospital Board Member	04/06- Present
Chairman of William E. Kahlert Endowment for Urological Research	01/07-Present
Vice President, William E. Kahlert Foundation	03/10- Present

COURSE FACULTY

Laparoscopic Urologic Surgery	4/3-5/92
Office of Continuing Medical Education	
Harvard Medical School and Division of Urology	
Brigham and Women's Hospital	
Pediatric Endourology and Laparoscopic Surgery	4/1-4/93
Office of Continuing Medical Education	
Harvard Medical School and Division of Urology	
The Children's Hospital	
Management of Urinary Incontinence	6/24/95
Greater Baltimore Medical Center	6/14/97
• Course Co-Director	
Advanced Management of Urinary Incontinence	10/16-18/98
Boca Raton, FL	
• Course Co-Director	
Management of Complex Urinary Incontinence and Pelvic Organ Prolapse	4/25-26/2003

Baltimore, MD

- Course Co-Director

Surviving Cancer in the 21st Century

2/21/2009

- Speaker

PATENTS

Inflatable Vaginal Pessary, U.S. Patent # 5,603,685

Inflatable Vaginal Pessary, U.S. Patent # 5,611,768

PUBLICATIONS

Ryan, Huo, Demers, Beer, Lacerna and The Zometa US05 Investigators: **Ronald Tutrone**, PI: Zoledronic Acid Initiated During the First Year of Androgen Deprivation Therapy Increases Bone Mineral Density in Patients With Prostate Cancer. *Journal of Urology* 176; 972-977, September 2006.

Price, Stein, Sieber, **Tutrone RF**, Bailen, Goluboff, Burzon, Bostwick and Steiner: Tormifene for the Prevention of Prostate Cancer Among Men with High-Grade Prostatic Intraepithelial Neoplasia: Results of a Double-Blind, Placebo-Controlled, Phase IIB Clinical Trial. *Journal of Urology* 176: 965-971, September 2006.

Valiquette, Young, Moncada, Porst, Vezina, Stancil, Edmunds, Montorsi and The Vardenafil Investigators: **Ronald Tutrone**, PI: Sustained Efficacy and Safety of Vardenafil for Treatment of Erectile Dysfunction: A Randomized, Double-Blind, Placebo-Controlled Study. *Mayo Clinic Proceedings*; 80 (10):1291-1297 October 2005.

Gaylis FD, Ignatoff JM, Amling CL, **Tutrone RF**, Cosgrove DJ, Prostate Cancer in Men Using Testosterone Supplementation and Role of Physician Specialty in Diagnosis. *Journal of Urology* 174: 534-538, August 2005.

Dunn JS, Bent AE, **Tutrone RF**, Elkermann RM: Acute Renal Failure caused by Complete Bladder Eversion through a Vesicovaginal Fistula. Accepted by *International Urogynecology*.

Staskin DR, Bavendam T, Miller J, Davilla GW, Diokno A, Knapp P, Rappaport S, Sand P, Sant G, **Tutrone RF**: Effectiveness of a Urinary Control Insert in the Management of Stress Urinary Incontinence: Early Results of a Multicenter Study. *UROLOGY* 47:629-636,1996.

Van den Abbeele AD, **Tutrone RF**, Berman RM, Baranowska-Kortzylewicz J, Barclay PD, Richie JP, Adelstein SJ, Kassis AI: Tumor-Targeting Potential of Radioiodinated Dododeox Yuridine in Bladder Cancer: Evaluation in Tumor-Bearing Rats. *J. Nuclear Medicine*, 37:315-320,1996.

Sand P, Bavendam T, Davilla G, Diokno A, Karram M, Knapp P, Miller J, Rappaport S, Sant G, Staskin D, **Tutrone RF**: The Effect of a Urinary Control Insert on Quality of Life in Incontinent Females. *Obstetrics and Gynecology*, 1996. *International Urogynecology Journal* 1999;10:100-105.

Tutrone RF, Ball RA, Ornitz DM, Leder PA, Richie JR: Benign Prostatic Hyperplasia in a Transgenic Mouse: A New Hormonally Sensitive Investigatory Mode. *J. Urol.*, 149:633-639, 1993.

Tutrone RF, Capelouto CC, Kavoussi LR: The Role of Laparoscopy in the Management of Prostate Cancer. In Wein AF, Malkowicz SB eds. Controversies in the Prostate Cancer. Part 11. Philadelphia: CoMed Communications; 1993.

Tutrone RF, Ball RA, Ornitz D, Leder PA, Richie JP: Benign Prostatic Hyperplasia in a Transgenic Mouse: A New Hormonally Sensitive Model. American College of Surgeons, Surgical Forum, XVII: 1991.

Van den Abbeele AD, Baranowska-Kortzylewicz J, Adelstein SJ, Carvalho PA, **Tutrone RF**, Richie JP, Wen PYC, Black PMcl, Mariani G, Kassis, AI: Diagnostic and Therapeutic Applications of Auger-Electron-Emitting 5-(¹²³/¹²⁵) Iodo-2'-Deoxyuridine in Cancer. Biophysical Aspects of Auger Processes, American Association of Physicists in Medicine. Symposium Series Number 8:372-295, 1992.

ABSTRACTS

Tutrone RF, Cookson MS, Lihou C, Harper SQ, Lang Z, Thomas H: Retrospective effectiveness and Safety of Valrubicin in Non-Muscle-Invasive Bladder Cancer following Reapproval. NC-AUA, October 10-13, 2012 Chicago, IL

Tutrone RF, Bent A, McLennan M, Goldstein DS: Treatment of ISD Urinary Incontinence in Women Using Autologous Chondrocytes-Preliminary Results. Hilton Head, SC, October 3-6, 1999.

McAlear H, **Tutrone RF**: Biofeedback/Electrical Stimulation Therapy in the Management of Urinary Incontinence in a Clinical Urology Practice. Annual Meeting AUA, Las Vegas, NV. April 23-28, 1995.

Duckett M, Goldstein DS, Goldstein RB, Shackelford N, Baker LS, **Tutrone RF**: The Use of Oral Trazodone for the Treatment of Venogenic Erectile Dysfunction. Annual Meeting AUA, Las Vegas, NV. April 23-28, 1995.

Capelouto CC, Raymond SA, Case CR, **Tutrone RF**, Richie JP, Vickers MA: Intraoperative Tumescence Monitoring During Radical Prostatectomy. Annual Meeting AUA, San Antonio, TX. May 15-20, 1993.

Tutrone RF, O'Donnell MA, Goldstein DS, Brodsky G, DeWolf WC, Richie JP: Intravesical Therapy with BCG for Transitional Cell Carcinoma of the Bladder in a Rat Model. Annual Meeting AUA, San Antonio, TX. May 15-20, 1993.

Tutrone RF, Goldstein DS, O'Donnell MA, Brodsky G, DeWolf WC, Richie JP: Intravesical Therapy with BCG for Transitional Cell Carcinoma of the Bladder in a Rat Model. Joint Annual Meeting Northeastern/New England Section AUA, Toronto, Ontario, Canada. September 13-16, 1992.

Tutrone RF, Ball RA, Ornitz D, Leder PA, Richie JP: Benign Prostatic Hyperplasia in a Transgenic Mouse: A New Hormonally Sensitive Investigatory Model. Annual Meeting AUA, Washington, D.C. May 10-14, 1992.

Van den Abbeele AD, **Tutrone RF**, Berman RM, Baranowska-Kortylewicz J, Barclay PD, Richie JP, Adelstein SJ, Kassis AI: 5-(¹²³I/¹²⁵I) Iodo-2'-Deoxyuridine (*IUdR) as Diagnostic and Potential Therapeutic Agents for Bladder Cancer. Annual Radiation Research Society. Salt Lake City, UT. March 14-18, 1992.

Van den Abbeele AD, Barclay PD, **Tutrone RF**, Goldstein DS, Makrigiorgos GM, Berman RM, Weinberg DS, Richie JP, Adelstein SJ, Kassis, AI.: Radioiodinated IUdR (*IUdR) Uptake in Exfoliated Cells Obtained from Patient with Bladder Cancer: Implications for Diagnosis and Therapy. Annual Radiation Research Society, Salt Lake City, UT. March 14-18, 1992.

Tutrone RF, Ball RA, Ornitz D, Leder PA, Richie JP: Benign Prostatic Hyperplasia in a Transgenic Mouse: A New Hormonally Sensitive Mode. Annual Meeting New England Section AUA, Dixville Notch, NH. October 6-9, 1991.

Tutrone RF, Bauer SB, Peters CA, Mandell, J, Colodny AH, Retik AB: Physiologic Basis for Continence in the Mitrofanoff Principle. Annual Meeting AUA, Toronto, Canada. June 2-6, 1991.

Richie JP, Ball RA, **Tutrone RF**, Ornitz D, Leder PA: Int-2 Transgenic Mouse: New Investigatory Model for BPH. American Association of Genitourinary Surgeons, Annual Meeting, Naples, FL. April 4-6, 1991.

Tutrone RF, Bauer SB, Mandell J, Colodny AH, Retik AB: The Use of the Mitrofanoff Principle for Continent Urinary Diversion. Annual Meeting New England Section AUA, Edinburg, Scotland. October 21-27, 1990.

Tutrone RF, Laungani G: A New Method for Treatment of Intra-urethral Hair Growth Following Urethroplasty. Annual Valentine Resident Essay Meeting, New York Academy of Medicine. March 30, 1988.

VIDEOS

Tutrone RF, Bailey RW: Laparoscopic Ureterolysis for Ovarian Vein Syndrome. Annual Meeting AUA, Las Vegas, Nevada. April 23-28, 1995.

Capelouto CC, **Tutrone RF**, Kavoussi LR: Laparoscopic Tissue Dissection Utilizing the Cavitational Ultrasonic Surgical Aspirator. Eleventh World Congress on Endourology, Florence, Italy. October 20-23, 1993.

Rosenberg M, **Tutrone RF**, Kavoussi L, Clayman R: Laparoscopic Radical Nephrectomy. Eleventh World Congress on Endourology, Florence, Italy. October 20-23, 1993.

Rosenberg MT, **Tutrone RF**, MacLeod SA, Clayman RV, Kavoussi LR: Laparoscopic Radical Nephrectomy. Video Urology '93 5th World Congress, Orlando, Florida. June 24-27, 1993.

Rosenberg MT, **Tutrone RF**, MacLeod SA, Clayman RV, Kavoussi LR: Laparoscopic Radical Nephrectomy. Annual Meeting AUA, San Antonio, TX. May 15-20, 1993.

Capelouto CC, O'Donnell MA, **Tutrone RF**, Kavoussi LR: Laparoscopic Tissue Dissection Utilizing the Cavitron Ultrasonic Surgical Aspirator. Annual Meeting AUA, San Antonio, TX. May 15-20, 1993.

Tutrone RF, Silverman SC, Kikinis R, Chernoff DM, Loughlin KR, Richie JP: Partial Nephrectomy with 3-D Image Enhancement. Countway Urology Grand Rounds, Harvard Medical School, Boston MA, October 3, 1992.

Ho, GT, **Tutrone RF**, Colodny A, Kavoussi LR: Endoscopic Hydrocele Ablation. Videourology '92, 4th World Congress, Monte-Carlo. October 1-3, 1992.

CLINICAL RESEARCH

Dendreon Corporation

8/2012-Present

- Principal Investigator
A Registry of Sipuleucel-T Therapy in Men with Advanced Prostate Cancer

Medivation, Inc.

7/2012-Present

- Principal Investigator
A Multicenter Phase 2, Randomized, Double Blind, Efficacy and Safety study of Enzalutamide vs. Bicalutamide in Men with Prostate Cancer who Have Failed Primary Androgen Deprivation Therapy

Augmenix , Inc.

4/2012-Present

- Sub Investigator
Evaluation of SpaceOAR System when used to Create Space Between the Rectum and Prostate in men Undergoing Image Guided –Intensity Modulated Radiation Therapy (IG-IMRT) for Localized Stage T1-T2 Prostate Cancer: A Randomized , Multicenter, Parallel Arm Controlled Clinical Trial

GTx, Inc.

8/2012-Present

- Principal Investigator
Phase 2 Open Label Study of the Effect of GTx-758 as secondary hormonal therapy on serum PSA and serum free Testosterone levels in men with

Metastatic Castration resistant prostate Cancer maintained on Androgen Deprivation Therapy

- Nymox Pharmaceuticals, Inc. 7/2012-Present
- Principal Investigator
A Phase 2 Multicenter Prospective Open Label Clinical Safety and Efficacy Evaluation of Injection of NX-1207 for the Treatment of Low Risk, Localized (T1c) Prostate Cancer
- Aragon Pharmaceuticals, Inc. 10/2011-Present
- Principal Investigator
An Open-Label, Phase1/2 Safety, Pharmacokinetic, and Proof of Concept Study of ARN-509 in Patients with Progressive Advanced Castration-Resistant Prostate Cancer.
- NeoTract, Inc. 8/2011-Present
- Sub-Investigator
The L.I.F.T. Pivotal Study – Luminal Improvement Following Treatment of Prostatic Tissue Approximation for the Treatment of Lower Urinary Tract Symptoms
- Serenity Pharmaceuticals, Corp. 6/2011-Present
- Principal Investigator
A Randomized, Double Blind, Placebo Controlled, Parallel Group, Multicenter Study to Investigate the Efficacy and Safety of SER120 Nasal Spray Formulations in Patients with Nocturia
- GTx, Inc. 10/2011-6/2012
- Principal Investigator
Phase 2, Open Label, Dose finding study of the Effect of GTx-758 on Total and Free Testosterone levels in Men with Prostate Cancer Compared to a Luteinizing Hormone Releasing Hormone Agonist
- Nymox Pharmaceuticals, Inc. 1/2011-Present
- Principal Investigator
A Phase 3, Multicenter Prospective Open Label Clinical Safety Evaluation of Re-Injection of NX-1207 for the treatment of BPH: Two Doses 1-7 Years Apart

- Endo Pharmaceuticals, Inc. 3/2011-Present
- Principal Investigator
A Phase 3, Randomized, Active-Controlled, Open-Label, Multicenter Study to Evaluate the Efficacy and Safety of EN3348 (MCC) as Compared with Mitomycin C in the Intravesical Treatment of Subjects with BCG Recurrent or Refractory or Refractory Non-Muscle Invasive Bladder Cancer
- BioServe Biotechnologies, Ltd. 1/2011-Present
- Principal Investigator
Multi-Site, Collection of Anonymized Biological Specimens and Phenotypic Data from a Large Cohort of Subjects for Inclusion in a Repository and Use in Genomic (from DNA and RNA), Serologic and Metabolic (from Serum) and Proteomic (from Protein) research studies (Pro00005300)
- Auxilium Pharmaceuticals, Inc. 11/2010-6/2012
- Principal Investigator
A Phase 3, Double Blind, Randomized, Placebo-Controlled Study of the Safety and Effectiveness of AA4500 Administered Twice per Treatment Cycle for up to Four Treatment Cycles (2x4) in Men with Peyronie's Disease (Aux-CC-803)
- Focus Surgery, Inc. 9/2010-6/2011
- Principal Investigator
A Multicenter Clinical Study of the Sonablate® (Sonablate for the Treatment of locally Recurrent Prostate Cancer with HIFU (STAR Trial)
- Nymox Pharmaceuticals, Inc. 10/2009-Present
- Principal Investigator
Phase 3, Multicenter, Prospective, Randomized, Parallel-Group Placebo-Controlled Double-Blind Clinical Evaluation of NX-1207 for the Treatment of BPH
- Ferring Pharmaceuticals, Inc. 10/2009-6/2012
- Principal Investigator
A Randomized, Controlled, Open-Label Trial of Degarelix Intermittent Therapy vs. Continuous Androgen Deprivation Therapy with Leuprolide or Degarelix in

Patients with Carcinoma of the Prostate with Biochemical Failure after Localized Therapy

- Spectrum Pharmaceuticals, Inc. 4/2009- 6/2012
- Principal Investigator
A Multi-Center, Randomized, Placebo-Controlled, Double-Blind, Phase 3 Trial of Single-Dose Intravesical EOquin® as a Surgical Adjuvant Instilled in the Early Postoperative Period in Patients Undergoing Transurethral Resection for Noninvasive Bladder Cancer
- Sanofi-Aventis, Inc. Investigator Initiated Trial 4/2009-Present
- Principal Investigator
A Double-Blind, Placebo-Controlled, Crossover Study to Evaluate the Efficacy of Alfuzosin in Treating Men with **ED and Mild LUTS**.
- Bioniche Life Sciences, Inc. 5/2008-3/2012
- Principal Investigator
Open-Label, Multi-Center Study of the Efficacy and Safety of MCC in the treatment of Patients with Non-Muscle Invasive (Superficial) **Bladder Cancer** at High Risk of Progression and who are Refractory to BCG.
- Sanofi-Aventis, Inc. 1/2007-12/2010
- Principal Investigator
A Randomized, Open Label, Multicenter, Phase III, 2-Arm Study of Androgen Withdrawl with Leuprolide +/- Docetaxel for Clinically Asymptomatic **Prostate Cancer** Subjects with a Rising PSA Following Definitive Local Therapy.
- Boston Scientific 5/2007-Present
- Principal Investigator
Post Marketing Study using Prolieve™ for the treatment of **Benign Prostatic Hyperplasia (BPH)**.
- Amgen 3/2007-Present
- Principal Investigator
A Randomized, Double-Blind, Placebo-Controlled, Mutli-Center Phase 3 Study of Denosumab on Prolonging Bone Metastasis-Free Survival in Men with Hormone-Refractory **Prostate Cancer**.

- Solvay 3/2007- 2008
- Principal Investigator
A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Efficacy and Safety Study of **Testosterone** Gel 1.62% for the Treatment of Hypogonadal Men.

- Merck 7/2006-2007
- Principal Investigator
A multi-center, double-blind, randomized, placebo-controlled, parallel-group, dose-ranging study of L-000796568 in postmenopausal women with **overactive bladder**.

- Gtx, Inc. 1/2005-7/2009
- Principal Investigator
Phase III
A Randomized, Double-Blind, Placebo-Controlled, Multicenter Efficacy and Safety Study of Toremifene Citrate for the **Prevention of Prostate Cancer** in Men with High Grade Prostatic Intraepithelial Neoplasia (PIN).

- Sanofi- Synthelabo, Inc. 10/2003-9/2009
- Investigator Initiated Protocol
An Open Label Study of Serum Testosterone Recovery and PSA after Six Months of Neo-Adjuvant Treatment with Eligard™ 22.5mg with Radiation Therapy in Patients with Early Stage **Prostate Cancer**.

- GlaxoSmithKline, Inc. 6/2003-9/2010
- Principal Investigator
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**.

Schwarz Biosciences

7/2002-2004

- Principal Investigator
A Phase II, parallel group, stratified, randomized, double-blind, placebo-controlled trial to investigate the efficacy and safety of multi-dosages of fesoteridine in subjects with **overactive bladder** showing either involuntary detrusor contractions or normal findings during the baseline urodynamic assessment.

Yamanouchi Pharma America

6/2004- 11/2005

- Principal Investigator
Phase 3b
An Open Label Multicenter Study to Assess The Efficacy and Safety of Daily Oral Administration of 5 and 10 mg Vesicare (Solifenacin Succinate) in Patients Who Wish to Switch from Detrol LA® (Tolterdine Tartrate Extended Release) For The Treatment of **Overactive Bladder** Symptoms/YPA905-UC-006.

Dendreon Corporation

6/2004-9/2006

- Principal Investigator
A Randomized, Double-Blind, Placebo Controlled Phase 3 Trial of Immunotherapy with Autologous Antigen Presenting Cells Loaded with PA2024 (Provenge ®, APC8015) in Asymptomatic Subjects with Gleason Sum ≤ 7 Metastatic, Androgen Independent **Prostatic Adenocarcinomas**

ICOS Corporation

6/2003-9/2005

- Sub-Investigator
A Phase II, randomized, double-blind, placebo-controlled study of the safety and efficacy of RTX topical solution in patients with **interstitial cystitis**.

Merck, Inc.

6/2003- 7/2005

- Principal Investigator
A double-blind, randomized, placebo-controlled, multicenter study to evaluate the effects of rofecoxib in decreasing the risk of **prostate cancer** (VIP study).

Novartis Pharmaceuticals

6/2003-10/2005

- Principal Investigator

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**.

Pfizer, Inc.

6/2003-1/2005

- Principal Investigator
A multicenter, randomized, parallel-group, double-blind, placebo-controlled, flexible dose escalation study to evaluate sexual and relationship satisfaction in the female partner of men with **erectile dysfunction** treated with Viagra® (sildenafil citrate) in the US.

GlaxoSmithKline, Inc.

6/2003-1/2005

- Principal Investigator
A randomized, double-blind, parallel-group, placebo-controlled study evaluating the efficacy, safety and reliability of 10mg vardenafil administered for 12 weeks compared to placebo in subjects with **erectile dysfunction** and a demonstrated successful first response to 10mg vardenafil.

Schwarz Biosciences

8/2003-12/2004

- Principal Investigator
Two phase extension trial of SP668 to investigate the safety and tolerability of sustained release fesoterodine in subjects with **overactive bladder**. A double-blind phase followed by an open-label phase extension phase.

Hoffman-La Roche, Inc.

12/2002-1/2005

- Principal Investigator
NN16378 open-label extension for treatment of **incontinent** patients who have completed an Ro115-1240 study.

Hoffman-La Roche, Inc.

5/2002-11/2004

- Principal Investigator
Randomized, double-blind, placebo-controlled, dose finding study to evaluate the effects of a partial alpha adrenoceptor agonist, Ro115-1240, in women with stress **urinary incontinence** or mixed urinary incontinence.

GTx, Inc.

5/2002-5/2003

- Principal Investigator
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.

- Pharmacia 5/2002-12/2002
- Principal Investigator
A 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)**.
- Kyowa Pharmaceutical, Inc. 5/2002-12/2002
- Principal Investigator
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.
- Health Decisions, Inc. 2001-7/2003
- Principal Investigator
A multicenter, pivotal Phase III, two-arm randomized placebo-controlled study to determine the chemoprevention efficacy and safety of 60mg daily of GTX-006 against high-grade **prostate intraepithelial neoplasia (PIN)**.
- Curon Corp, LLC 7/2001-5/2002
- Principal Investigator
Two-arm randomized, double-blind pilot herbal study for treatment of **ureteral calculi**.
- Medtronic, Inc. 2001-2004
- Principal Investigator
Medtronic Interstim® Patient Registry
- Boehringer Ingelheim 4/2001-2/2002
- Principal Investigator
A Phase II, double-blind, randomized, parallel-group design, multicenter study of FLOMAX® capsules, 0.4mg daily versus placebo in male patients with acute **urinary retention** related to benign prostatic hyperplasia.
- Eli Lilly 2000-8/2006
- Principal Investigator
Open Label. Long-term monitoring of safety in subjects treated with duloxetine for **stress urinary incontinence**.
- Eli Lilly 9/2000-2/2002
- Principal Investigator
A Phase III efficacy and safety of duloxetine compared with placebo in subjects with **stress urinary incontinence**.

- Reprogenesis/Curtis 2000/2002
- Principal Investigator
A Phase II randomized, double-blind study comparing chondrogel (autologous chondrogel in alginate hydrogel) and alginate hydrogel for the treatment in women with ***stress urinary incontinence*** due to ISD.
- TAP Holdings, Inc./Quintiles 1/2000-11/2001
- Principal Investigator
A Phase II, 12-week safety and efficacy study of oral TAK-637 versus placebo in subjects with ***overactive bladder***.
- Pharmacia & Upjohn 1/2000–10/2001
- Principal Investigator
A patient acceptability study of a once-daily formulation of tolterodine. A Phase IIIB open-label, single-arm trial in adult patients with ***overactive bladder*** and symptoms of urinary frequency/urgency and/or urge incontinence.
- Bayer, Inc. 1/2000-8/2000
- Principal Investigator
A randomized, open-label, comparative, experience trial of ciprofloxacin hydrochloride (250 to 500mg bid for 3-14 days) versus trimethoprim/sulfamethoxazole (160/800mg bid for 10-14 days) in the treatment of outpatient adults with ***lower urinary tract infections***. Protocol 100231.
- TAP Pharmaceutical Inc. 2000-11/2001
- Principal Investigator
A Phase II, 52-week extension study to evaluate long-term safety of oral TAK-637 in subjects with ***overactive bladder***.
- Pharmacia & Upjohn 1999-2003
- Principal Investigator
A national Phase II trial of Interferon Alfa 2B (Intron A) plus BCG for treatment of ***superficial bladder cancer***.
- Reprogenesis 1999-2001
- Principal Investigator
Protocol for the re-treatment with chondrogel (chondrocyte-alginate gel suspension) of patients enrolled in Reprogenesis' protocol 96-03.
- Pharmacia & Upjohn 1998-1999
- Principle Investigator

A multicenter, pivotal Phase III two-arm, long-term safety and efficacy of tolteradine prolonged release capsules.

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| TAP Holdings, Inc. | 1998-2000 |
| • Principal Investigator | |
| A Phase III long-term, open label, flexible dose, safety extension study of apomorphine SL tablets in a special population for the treatment of male erectile dysfunction . | |
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| TAP Holdings, Inc. | 1998-1999 |
| • Principal Investigator | |
| A Phase III safety and efficacy study of two fixed doses of apomorphine SL tablets versus placebo in the treatment of male erectile dysfunction in patients with controlled diabetes. | |
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| Eli Lilly and Company | 1998-1999 |
| • Principal Investigator | |
| Duloxetine versus placebo in the relief of stress urinary incontinence (Phase III) | |
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| Pharmacia & Upjohn | 1998-1999 |
| • Principal Investigator | |
| Dose escalation study with tolterodine in patients with overactive bladder. A single-blind study in patients with symptoms of overactive bladder including urinary urgency and frequency with or without urge incontinence. | |
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| American Medical System/Pfizer | 1996-2003 |
| • Principal Investigator | |
| A multicenter prospective cohort study to evaluate the safety and effectiveness of the American Medical Systems' Ambicor inflatable penile prosthesis . | |
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| Reprogenesis, Inc. | 1996-1999 |
| • Principal Investigator | |
| Protocol for the clinical investigation of an autologous tissue implant for the treatment of urinary incontinence . | |
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| Medtronic, Inc. | 1996-1998 |
| • Principal Investigator | |

Randomized multicenter evaluation of the safety and effectiveness of the sacral nerve stimulation system for the treatment of *urinary dysfunctional voiding* patterns.

Upjohn Company

1994-1996

- Principal Investigator
Phase III study of oral bropiramine versus intravesical BCG in adult patients with BCG-naïve *bladder carcinoma in-situ*.

R.W. Johnson Pharmaceuticals

1994-1995

- Co-Investigator
Multicenter, double-blind, randomized study to compare the safety and efficacy of oral levofloxacin with that of ciprofloxacin HCL in the treatment of complicated *urinary tract infections* in adults.

Uromed Corporation

1993-1998

- Principal Investigator
Clinical investigation of a urethral occlusion device for the treatment of *stress urinary incontinence*.

SmithKline Beecham Pharmaceuticals

1993-1995

- Co-Investigator
A one-year, multicenter, double-blind comparison of the effects of once-daily dosing with three dose levels of SK&F 105657 or placebo in the treatment of symptomatic *BHP*, with six-month untreated follow-up.

ALZA Corporation

1993-1995

- Co-Investigator
Acceptability of Testerderm *testosterone*, transdermal systems in private clinical practice.