

Curriculum Vitae
Lawrence I. Karsh, M.D.

CURRICULUM VITAE

LAWRENCE I. KARSH, M.D., F.A.C.S.
2777 Mile High Stadium Circle
Denver, CO 80211
303-825-8822 (office)
303-825-4022 (fax)

EDUCATION:

University of Colorado, 1973
B.A., English, Chemistry, Biology

University of Health Sciences Chicago Medical School, 1978, M.D.

POST-DOCTORAL TRAINING:

University of Colorado School of Medicine, Denver, CO Department of Surgery,
Surgeon Chief, Thomas Starzl, M.D.

1978-1979 Surgical Intern

1979-1980 Surgical Resident

Harvard Medical School, Boston, MA

Brigham's and Women's Hospital

Division of Urological Surgery,

Urologist-in-chief, Ruben Gittes, M.D. 1980-1981 Junior Resident in Urology

1981-1982 Research Fellow in Urology

1982-1983 Senior Resident in Urology

1983-1984 Chief Resident in Urology

WORK HISTORY:

Private Practice-The Urology Center of Colorado-2006-present

Private Practice-Urology Surgical Associates/Western Urologic Associates, 10/84 to 2006

Assistant Clinical Professor of Surgery/Urology-University of Colorado Health Sciences Center,
1985 to present

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BOARD CERTIFICATION:

National Board of Medical Examiners, 1979
American Board of Urology, 1986
Re-certified American Board of Urology, 1993 – 2006
Re-certified American Board of Urology, 2003 - 2016

PROFESSIONAL MEMBERSHIPS/ORGANIZATIONS:

American Urologic Association, 1985 to Present
Fellow-American College of Surgeons, 1987 to Present
Denver Academy of Surgery, 1988 to present
National Cancer Institute Investigator-38724-Epiration-9/2012
SWOG- 2006 to Present
RTOG- 2009 to Present
Society of Urologic Oncology Clinical Trials Consortium;
Bladder Cancer Subcommittee 2009-Present

SPECIALTY INTERESTS:

Director of Research The Urology Center of Colorado
Adult Reconstructive Surgery, including Continent Urinary Diversion
Oncology
Stone Disease
Incontinence
Prostate Disease

MEDICAL LICENSURE:

Colorado, 1979 to Present

CERTIFICATES AND AWARDS:

Brownes Resident, Urodynamic Prize, “Urology Times”, Vol. 10, No.4, April 1982
Investigator Support Initiative Training Course sponsored by Pfizer, Colorado Springs, Colorado, June 2003.

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HOSPITAL AFFILIATIONS:

Exempla Lutheran Medical Center

Exempla Saint Joseph Hospital

Centura St. Anthony Central and North Hospital

Porter Hospital

Presbyterian - St. Luke's

Rose Medical Center

Swedish Medical Center

Craig Rehabilitation Hospital

ACADEMIC APPOINTMENTS:

Department of Surgery, Harvard Medical School, Boston, MA
1980-1984, Clinical Fellow in Surgery

Department of Surgery, University of Colorado Health Sciences
Center, Denver, CO 1985-Present,
Assistant Clinical Professor of Surgery/Urology

ADVISORY BOARD APPOINTMENTS:

Bladder Cancer Advisory Network (BCAN)

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Amgen
GlaxoSmithKline
Pfizer
Novartis
Centocor Ortho Biotech
Sanofi-Aventis

LANGUAGES:

English/Spanish

PODIUM PRESENTATIONS:

Western Urologic Research Center Investigator Training Program-
AUA National Meeting-
“Left Renal Venous Hypertension Caused by SMA Compression”
Boston, MA, February, 1981

New England Section AUA-
“Renal Artery Aneurysms”
Palm Beach, FL, September, 1981
Society for Bone and Mineral Metabolism -
San Francisco, CA, June, 1982

Vasectomy Panel– (Television)
“Exercise Induced Increases in Plasma Calcium Concentration Occur
Equally in Normal and Thyroidectomized Humans”
Boston, MA, July, 1982

New England Section AUA-
Spermatogenesis It’s Effect upon the Immune Rejection of Intratesticular Grafts
Bermuda, September, 1983

Phoenix Urological Society-
“Continent Urinary Diversion”
Phoenix, AZ, September, 1988

Colorado Chapter of the American College of Surgeons-
“Continent Urinary Diversion”

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Colorado Springs, CO, May, 1988

Kansas City Urological Society-
“Continent Urinary Diversion”
Kansas City, KS, May, 1988

A Primary Care Perspective Symposium-
“BPH and Other Urologic Disorders”
Denver, CO, November, 1996

Primary Care Education Series-
“Diagnosis and Management of Erectile Dysfunction”
Denver, CO, November, 1996

Primary Care Education Series-
“Current Perspectives in Management of Benign Prostatic Hyperplasia”
Denver, CO, November, 1997

Primary Care Symposium-
“BPH - Historical Review and Management”
Denver, CO, April, 1998

Centura Seniors Program
“Prostate Cancer and Treatment”
Denver, CO, July, 1998

St. Anthony Family Resident Program-
“Treating Erectile Dysfunction”
Denver, CO, June 1998

Large Urology Group Practice Association-
“Bone Health in Patients with Metastatic Prostate Cancer”
Chicago, Illinois, November 6, 2009

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Mid Atlantic AUA 68th Annual Meeting - “A phase III Randomized trial of Denosumab vs. Zoledronic Acid in patients with bone metastases from castration resistant prostate cancer”
Farmington, PA, September 25, 2010

Cleveland Clinic SUO Clinical Trials Consortium Therapeutic Course-
“The Essential Role in Rank Ligand Pathway”
Cleveland, Ohio, October 8, 2010

Cleveland Clinic SUO Clinical Trials Consortium Therapeutic Course-
“Clinical Trials Experience and Good Clinical Practice”
Cleveland, Ohio, October 8, 2010

New England AUA 79th Annual Meeting-“A phase III Randomized trial of Denosumab vs. Zoledronic Acid in patients with bone metastases from castration resistant prostate cancer”
Providence, Rhode Island, October 22, 2010

SUO Clinical Trials Consortium-
Bladder Cancer Sub-Committee
National Institutes of Health
Bethesda, Maryland, December 9, 2010

MODERATOR/INSTRUCTOR:

Investigator Training Meeting
Training Course for Clinical Trials Investigators
(Sponsored by University of Miami School of Medicine)
Westin Tabor Center
Denver, Colorado, November 12, 2005

The Urology Center of Colorado Good Clinical Practice Workshop Instructor
Sponsored by Pfizer Pharmaceuticals
The Urology Center of Colorado
Denver, Colorado, March, 2006

The Urology Center of Colorado Good Clinical Practice Workshop Instructor-
Sponsored by GlaxoSmithKline
The Urology Center of Colorado
Denver, Colorado, March, 2007

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The Urology Center of Colorado Good Clinical Practice Workshop Instructor-
Sponsored by Tap Pharmaceuticals
The Urology Center of Colorado
Denver, Colorado, March, 2008

PUBLICATIONS:

Karsh, L.I., Richie, J.P. Ed. B. Eiseman, W.A. Robinson and G. Steele, Jr.:
“Renal Cell Carcinoma in Follow-up of the Cancer Patient”
New York Thieme-Stratton, Inc., Vol. I, Chapter 22, pp 116-120, 1982.

Karsh, L.I., Yalla, S.V., Faser, L.B., Finn, D.J., DeFelippo, N.P. Dyro, F.:
“Post-prostatectomy Urinary Incontinence”
Neurology-Urology Dynamics 1:77, 1982.

Karsh, L.I., Koyle, M.A., Kearney, G.P.:
“Renal Artery Aneurysms Assessed Non-invasively by Angiography”,
Urology Times, 10 (5):1, 1982.

Karsh, L.I., Whitmore, W.F., Gittes, R.F.:
“The Role of Germinal Epithelium and Spermatogenesis in the Privileged
Survival of Intratesticular Grafts”
Journal of Urology, 134:782, 1985.

Karsh, L.I., McDonald, J., Gittes, R.F.:
“Exercise Induced Increases in Plasma Concentrations Occur Equally in Normal and
Thyroidectomized Humans”
Surgical Resident.Comm., Vol 2, pp 113-118, 1987.

Karsh, L.I.:
“The Use of YAG Laser to Remove Marlex Strut from Kock Continent Urinary Reservoir”
Journal of Endourology, Vol. 7, Issue 1, pp 53-55, 1993.

CLINICAL RESEARCH PROJECTS: *(Principal Investigator for all the following enrollment met or exceeded):*

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- 01) Abbott 1994: “Phase III BPH”
- 02) Pfizer 1998: “Phase III Impotence”
- 03) Alza 1998-1999: “Phase III OAB”
- 04) Boehringer-Ingelheim 1998-2000: “Phase III Study for Men with BPH”
- 05) Boehringer-Ingelheim 2000 – 2001: “Phase II Study for Men with Non-bacterial Prostatitis”
- 06) NCI/Pharmacia 2000-Ongoing: “Phase IIb-III Chemo Prevention for Bladder Tumor Recurrence in High-Risk Patients”
- 07) Pfizer 2/2000-1/2002: “Phase III Anticholinergic for Urge Incontinence”
- 08) Pfizer 2000-3/2002: “Open-label Extension for Urge Incontinence”
- 09) Alza 2000-2001: “Phase III Safety Study of Males with BPH”
- 10) Barr 3/2001-5/2003: “Phase III Study for Men with Vasomotor Hot Flashes as a Result of Being Treated with Hormone Manipulation Therapy for Prostate Cancer”
- 11) Sample Acquisition for BLCA 3/2001: “For the Testing in the Diagnosis of Bladder Cancer”
- 12) Pfizer 5/2001: A1371027 “A Phase II Multi-Center, Placebo Controlled, Pilot Study to Determine the Efficacy of Darifenacin in the Treatment of Nocturnal Symptoms”
- 13) Pfizer 5/2001: A1371014 “A Phase III, Multi-center, Open Label, Continuation Study of the Long Term Safety, Toleration, Compliance and Efficacy of Controlled Release Darifenacin in Subjects with Overactive Bladder”
- 14) Boehringer-Ingelheim 6/2001-5/2002: “Phase III Study of Alpha-Blocker for Treatment of AUR”
- 15) Sanofi-Synthelabo 6/2001: “A Long Term Efficacy and Safety of Alfuzosin 10mg qd on the Risk of Acute Urinary Retention and the Need for Surgery in Patients with BPH. A Two-Year Randomized, Multi-Center, Double-Blind Parallel-Group, Placebo-Controlled Study”
- 16) Pfizer 9/2001: A1371001 “A Phase III, Multi-Center, Double-Blind, Randomized, Placebo Controlled, Parallel Group Study of the Efficacy and Safety of Controlled Release Darifenacin vs. Tolterodine in the Treatment of Subjects with Overactive Bladder”
- 17) Auxillium 9/2001: TG-205 “Evaluation of the Relationship between Genotype Expression Determined by DNA Analysis and Differences in Phenotypic Expression as Determined by Serum Testosterone Levels in Aging Males”
- 18) Eli Lilly & Co. 2001-1/2002: “Women with Stress Urinary Incontinence”
- 19) Eli Lilly & Co. 2001-Ongoing: “Open-Label Extension Protocol for Female Stress Urinary Incontinence”
- 20) Alza 11/2001–6/2002: “Phase IV OAB”
- 21) Auxillium 3/2002: TG-202.00 “An Evaluation of the Use of a Unique Testosterone Topical Gel Formulation in Males with a Testosterone level \leq 300 ng/dL”
- 22) Anthra Pharmaceuticals: A9601 “Intravesical AD 32 (N-Trifluoroacetyladrriamycin-14-valerate) vs. No Adjunctive Therapy Immediately Following Transurethral Resection in Patients with Multiple Superficial (Ta and T1) Bladder Tumors”

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- 23) Pfizer 4/2001–5/2002: “A Phase III Placebo-Controlled Pilot Study to Determine the Efficacy of Darifenacin in the Treatment of Nocturnal Symptoms of Overactive Bladder and Effects on the Quality of Sleep”
- 24) Pfizer 9/2001–4/2002: “Alpha-blocker for BPH”
- 25) Auxillium 2001–2002: “Phase III Study of Three Testosterone Products for Males with Hypogonadism”
- 26) Hoffmann LaRoche 2001: NN 16378 “A Randomized, Double-Blind, Placebo-Controlled, Dose-Finding Study to Evaluate the Effects of a Partial Alpha 1A/1 L-Adrenoceptor Agonist (Ro115-1240) in Women with Stress Urinary Incontinence”
- 27) Sanofi-Synthelabo 6/2001-7/2002: “Alpha-blocker for treatment of AUR”
- 28) Clinical Protocol 2002: “Sample Acquisition for BLCA-4 Testing in the Diagnosis of Bladder Cancer”
- 29) Pharmacia 4/2002-5/2003: “A Double Blind, Placebo Controlled, Randomized Study, to Evaluate the Effect of an Anticholinergic on Nocturia in Patients with Symptoms of Overactive Bladder”
- 30) Pfizer 6/2002: A2841018 “A Multi-Center, Double-Blind, Double-Dummy, Randomized, Placebo and Tamsulosin Controlled Parallel Group Study to Assess the Efficacy and Safety of UK-338,003 in Subjects with Lower Urinary Tract Symptoms Due to Benign Prostate Obstruction”
- 31) Sanofi-Synthelabo 4/2002–9/2002: EFC-4428 “A Double-Blind, Randomized, Parallel Group Study of Alfuzosin 10mg qd vs. Placebo in the Management of Acute Urinary Retention in Patients with a First Episode Due to BPH”
- 32) Schwarz Biosciences 10/2002: SP668A “A Phase II, Parallel Group, Stratified, Randomized, Double Blind, Placebo-Controlled Trial to Investigate the Efficacy and Safety of Three Different Dosages of Sustained Release Fesoterodine in Subject with Overactive Bladder Showing Either Involuntary Detrusor Contractions or Normal Findings During the Baseline Urodynamic Assessment”
- 33) Novartis 2002: “A 12-week, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Multi-Center Study to Evaluate the Efficacy of Darifenacin 15 mg qd on Increase in Warning Time, the Time from First Sensation of Urgency to Voiding, in Patients with OAB”
- 34) Auxillium 2002: TG-203.01 “An Open Label Use of a Unique Testosterone Topical Gel Formulation in Males with an Original Baseline Testosterone Level \leq 300 ng/dL”

- 35) GlaxoSmithKline 10/2003: ARI30019 “A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Compare the Efficacy, Safety and Tolerability of Oral Dutasteride (3.5mg) Administered Once Weekly to Placebo Administered Once Weekly for a 12 Month Period in Subjects with BPH”

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- 36) Pharmatech 3/2004: "Protocol PUI-02809"
- 37) Novartis Pharmaceuticals 2002: 03-034 US05 "A Double-Blind, Placebo-Controlled Study of the Effect of Zoledronic Acid on Bone Mineral Density in Men Receiving Androgen-37)"
- 38) Alza 8/2003: "Deprivation Therapy for Prostate Cancer Phase IIIb Study of an Oral Heparin-Based Compound for the Treatment of Interstitial Cystitis"
- 39) Eli Lilly 7/2003: "Open-label Study of a PDE5 Inhibitor for the Treatment of ED Administered "On Demand" in Men with Diabetes, HTN, and Other Special Populations" exceeded enrollment goal
- 40) Glaxo Smith Kline 4/2003–Ongoing: Phase III(b) "Study to Evaluate a 5 α -reductase Inhibitor in the Prevention of PCA in Men at High Risk"
- 41) GTX 9/2003-Ongoing: "A Phase III Study of a Selective Estrogen Receptor Modulator in the Prevention of Osteoporosis in Men on Androgen Deprivation Therapy for Prostate Cancer"
- 42) Novartis: 3/2003: "Late Phase Study to Evaluate the Use of a Bisphosphonate for the Prevention of Osteoporosis in Men on Androgen Deprivation Therapy for PCA"
- 43) Alza 6/2004: "A Randomized, Double Blind, Placebo-Controlled, Parallel Group Evaluation of the Efficacy and Tolerability of Two Different Doses of Elmiron for the Treatment of Interstitial Cystitis"
- 44) Eli Lilly 6/2004: H6D-MC-LVFN(b) "An Open Label Study to Evaluate the Efficacy and Safety of Tadalafil Administered "On Demand" to Men of Various Populations with Erectile Dysfunction"
- 45) Pharmatech 7/2004: "Trelstar Study for Advanced Prostate Cancer"
- 46) Novartis Pharmaceuticals 1/2005: 03-034 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"
- 47) Yamanouchi Pharma America 2/2005: "An Open Label Study of the Efficacy and Safety of 5 and 10mg Vesicare (solifenacin succinate) in Patients with Overactive Bladder Symptoms"
- 48) Glaxo Smith Kline 5/2005: VAR102108/BAY38-9456/11575 "Vardenafil 10mg Administered for 4 Weeks in a Fixed-Dose Regimen Compared to Placebo in Males with ED"
- 49) Roche 7/2005: NU18191 "Evaluation of Patients Who Completed More Than 180 Days of Active Treatment with Ro 115-1240"
- 50) Duramed 4/2005: DR-PCA-201 "A phase II, Randomized, Multi-Center, Placebo Controlled, Double-Blind, Dose-Ranging Clinical Trial To Study the Efficacy and Safety of 5mg, 15mg, or 25mg/day CyPat (Cyproterone Acetate) for the Treatment of Hot Flashes Following Surgical or Medical Castration of Prostate Cancer Patients"

- 51) Ortho-McNeil 9/2005: "A Multi-Center, Double-Blind, Randomized Study to Compare the Safety and Efficacy of Levofloxacin 750MG Once Daily for Five Days vs. Ciprofloxacin HCL 500MG Twice Daily for Ten Days in the Treatment of Complicated UTI or Acute Uncomplicated Pyelonephritis (CAPSS-349)"

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- 52) GTX Pharmaceuticals 10/2005: G300104 “A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of the Efficacy and Safety of Toremifene Citrate for the Prevention of Prostate Cancer in Men with High Grade PIN”
- 53) MediciNova 9/2005: MN-001-CL-002 Phase II “A Randomized Doubled Blind, Placebo-Controlled, Multi-Center Study to Evaluate the Efficacy and Safety of Two Dosing Regimens of MN-001 in Patients with Interstitial Cystitis”
- 54) Norvartis 5/2005: “A 12-Week, Randomized, Open-Label, Parallel-Group, Multi-Center Study to Evaluate the Efficacy, Safety and Tolerability of Enblex (Darifenacin) (with Voluntary Up-Titration from 7.5 mg qd to 15mg qd at 8 Weeks) Alone or in Combination with Behavioral Modification Program for Symptoms of Overactive Bladder”
- 55) Pfizer Protocol 1/2005: A6061023 “A Phase 2, 8-week Multi-Center, Randomized Double-Blind, Placebo Controlled, Parallel, Group Study Evaluating the Efficacy, Tolerability and Safety of (S,S)-Reboxetine (ONU-165442G) for Stress Urinary Incontinence in Women”
- 56) Pfizer 10/2005: A6121146 “A Multi-Center, Multiphase, Single Arm, Open Label, Study to Evaluate the Effects of Tolterodine ER In Conjunction with Behavioral Intervention on Subject Satisfaction and Overactive Bladder Symptoms (Urgency Urinary Incontinence (UUI), Urgency, Frequency) In Overactive Bladder Subjects, Who Were Dissatisfied With Their Most Recent Antimuscarinic OAB Medication Therapy”
- 57) Watson Pharmaceuticals 5/2005: SIO4009 “A Multi-Center Double-Blind Placebo Controlled Evaluation of the Safety of Silodosin in the Treatment of the Signs and Symptoms of Benign Prostatic Hyperplasia”
- 58) Watson Pharmaceuticals 5/2005: SIO4011 “A Multi-Center Open-Label Evaluation of the Safety of Silodosin in the Treatment of the Signs and Symptoms of BPH”
- 59) Amgen 2/2005: 2000050147 “A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Phase 3 Study of Denosumab on Prolonging Bone Metastases-Free Survival in Men with Hormone-Refractory Prostate Cancer”
- 61) GlaxoSmithKline 2/2005: VAR102108/BAY38-9456/11575 “A Randomized, Double-Blind, Crossover Study to Evaluate the Duration of Erection Following Vardenafil (10mg) Administered for 4 weeks in a Fixed-Dose Regimen Compared to Placebo in Males with ED”
- 62) Eli Lilly 5/2005: FIJ-US-SBCD “Evaluation of Efficacy and Safety of Duloxetine HCl in Women of Different Demographic Characteristics and Comorbidities with Stress UI”
- 63) GlaxoSmithKline 10/2005: NKB-105022 “A 12-Week Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Forced Titration, Proof of Concept Study to Assess the Efficacy, Safety and Tolerability and the Pharmacokinetic Profile of 60 mg vs. 120 mg of GW6799769 (GW679769) Administered Once Daily vs. Placebo in Women with Overactive Bladder”
- 64) Astellas 4/2006: 905-UC-008 “To Evaluate the Safety, Tolerability and Efficacy of Solifenacin Succinate (Vesicare) 5mg in Combination with Tamsulosin HCL (Flomax) for the Treatment of Residual Overactive Bladder Symptoms in Men Who are Treated with Flomax 0.4 mg for 4 Weeks”

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- 65) GlaxoSmithKline 5/2006: LEV106718 “A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Study Evaluating the Efficacy, Safety, and Duration of Erection of Flexible-Dose Vardenafil Administered for 12 Weeks Compared to Placebo in Subjects with Erectile Dysfunction and Dyslipidemia”
- 66) Novartis 6/2006: CDAR328A2404 “A 12-Week, Open-Label, Non-Randomized, Multi-Center Study to Evaluate the Patient’s Perception of Outcome After Treatment with Darifenacin in Overactive Bladder Patients Dissatisfied with Prior Anticholinergic Therapy”
- 67) Glaxo Smith Kline 6/2006: AVO105948 “A Randomized, Double-Blind, Placebo-Controlled Trial Assessing the Efficacy and Safety of Dutasteride in Extending the Time to Progression of Low-Risk, Localized Prostate Cancer in Men Who are Candidates for or Undergoing Expectant Management”
- 68) Amgen 8/2006: 2005103 “A Randomized, Double-Blind, Multi-Center Study of Denosumab Compared with Zoledronic Acid (Zometa) in the Treatment of Bone Metastases in Men with Hormone-Refractory Prostate Cancer”
- 69) Pfizer 2/2007: A6121146 “A Multi-Center, Multiphase, Single-Arm, Open-Label, Study To Evaluate the Effects of Tolterodine ER in Conjunction with Behavioral Intervention on Subject Satisfaction and Overactive Bladder Symptoms (Urgency Urinary Incontinence (UII), Urgency, Frequency) In Overactive Bladder Subjects Who Were Dissatisfied with Their Most Recent Antimuscarinic OAB Medication Therapy”
- 70) Indevous 8/2007: “A Two-Arm, Open-Label Randomized, Multi-Center Pharmacokinetic and Long-Term Safety Study of Intramuscular Injections of 750mg and 1000mg Testosterone Undeconoate in Hypogonadal Men”
- 71) Astellas 4/2007: 905-UD-008 “A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-Center Safety and Efficacy, Phase 4 Study of Vesicare (Solifenacin Succinate) or Placebo in Combination with Tamsulosin HCL for the Treatment of Residual OAB Symptoms”
- 72) Novartis 6/2007: “A Twelve-Week, Open-Label, Non-Randomized, Multi-Center Study to Evaluate the Patient’s Perception of Outcome After Treatment with Darifenacin in Overactive Bladder Patients Dissatisfied with Previous Anticholinergic Therapy”
- 73) GlaxoSmithKline 10/2007: AVO105943 “A Randomized Double-Blind Parallel Group Study Comparing Casodex 50mg Plus Casodex 50mg Placebo to plus Dutasteride 3.5mg Administered for 18 Months to Men with Prostate Cancer Who Have Failed First-Line Androgen Deprivation Therapy (Assessed by Rising PSA) Followed by a Two-Year Extension Phase”
- 74) Astellas 11/2007: 905-UC-010 “A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Phase 4, Multi-Center Study of Vesicare (Solifenacin Succinate) in OAB Subjects to Evaluate Symptom Bother and Health Related Quality of Life”
- 75) Astellas 11/2007: YM178 “A Randomized, Double-Blind, Parallel Group, Placebo Controlled, Multi-Center Study to Evaluate the Urodynamics and Safety of YM178 in Male Subjects with LUTS”
- 76) TheraVita 9/2007: THVD-101 “A Combination of an Antimuscarinic and Muscarinic

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Agonist vs. an Antimuscarinic Agent, Alone in Subjects with OAB”

77) Spectrum 9/2007: SPI-611 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”

78) Pfizer 10/2007: A0001009 “A Randomized Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Fesoterodine as an “Add-On” Therapy in Men with Persistent Overactive Bladder Symptoms Under Monotherapy of Alpha Blocker for Lower Urinary Tract Symptoms”

79) Sanofi-Aventis 3/2008: DRI6271 “A Placebo Controlled Randomized 12-Week Dose-Ranging, Double-Blind Study vs. Placebo using Tolterodine as Study Calibrator to Evaluate Efficacy and Safety of SSR240600C in Women with Overactive Bladder”

80) Tap Pharmaceutical 12/2007: L-PC07-169 “A Phase III, Multi-Center, Open-Label Trial to Evaluate the Efficacy, Safety and Pharmacokinetics of Two-6-Month Leuprolide Formulations in Subjects with Prostatic Adenocarcinoma”

81) Astellas 4/2007: 178-CL-047 “A Randomized, Double-Blind, Parallel Group, Active Controlled, Multi-Center Long-term Study to Assess the Safety and Efficacy of the Beta-3 Agonist YM178 (50 mg qd and 100 mg qd) in Subjects with Symptoms of Overactive Bladder”

82) Astellas 4/2007: 178-CL-049 “A Long-Term Phase III Study to Assess Safety and Efficacy of Beta-3 Agonist YM178 After Treatment of Subjects with OAB Symptoms”

83) Pfizer 4/2007: A0221014-1011 “A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multi-Center Trial to Evaluate the Efficacy and Safety of a Fesoterodine Flexible Dose Regimen in Patients with Overactive Bladder”

84) Pfizer 2/2008: A6061023 “A Phase 2, 8-Week Multi-Center, Randomized Double-Blind, Placebo Controlled, Parallel, Group Study Evaluating the Efficacy, Tolerability and Safety of (S,S)-Reboxetine (ONU-165442G) for Stress Incontinence in Women”

85) Pfizer 2/2008: DRI6271 “A Placebo Controlled Randomized, 12-week, Dose-Ranging, Double-Blind Study vs. Placebo, Using Tolterodine as a Study Calibrator, to Evaluate Efficacy and Safety of SSR240600C in Women with Overactive Bladder, Including Urge Urinary Incontinence”

86) Argos Pharmaceuticals 2008: AGS-003-006 “A Phase II Study Testing the Safety and Activity of AGS-003 as an Immunotherapeutic in Subjects with Newly Diagnosed Advanced Stage Renal Cell Carcinoma in Combination with Sunitinib

87) Merck 2009: 002-001 “A Phase I Investigation of the Safety, Tolerability and Immunogenicity of V934/V935 hTERT Vaccination in Cancer Patients with Selected Solid Tumors

88) Watson 2009: SIO8001 “A Multi-Center, Double-Blind, Placebo-Controlled Investigation of Silodosin in the Treatment of Subjects with Moderate to Severe Abacterial Chronic Prostatitis/Chronic Pelvic Pain Syndrome”

89) Ferring 2009: FE 200486 CS37 “A Randomized, Controlled, Open-Label Trial of Degarelix

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Intermittent Therapy vs. Continuous Androgen Deprivation Therapy with Leuprolide or Degarelix in Patients with Carcinoma of the Prostate with Biochemical Failure after Localized Therapy”

- 90) Ferring 2009: FE 200486 CS35 “An Open-Label, Multi-Center, Randomized, Parallel-Arm One-Year Trial, Comparing the Efficacy and Safety of Degarelix Three-Month Dosing Regimen with Goserelin Acetate in Patients with Prostate Cancer Requiring Androgen Deprivation Therapy”
- 91) Astellas 2009: 178-CL-074 2009 “A Phase III, Randomized, Double-Blind, Parallel Group, Placebo Controlled, Multi-Center Study to Assess the Efficacy and Safety of the Beta-3 Agonist YM178 (25 mg qd and 50 mg qd) in Subjects with Symptoms of Overactive Bladder”
- 92) Watson 2009: URO8004 “A Multi-Center, Randomized, Double-Blind, Parallel Group Evaluation of the Effectiveness and Safety of Urocyt Compared to Inactive Vehicle Control in Subjects with Interstitial Cystitis/Painful Bladder Syndrome”
- 93) Ferring 2010: 200486 CS36 “A Dose Finding, Multi-Center, Double-Blind, Randomized, Parallel, Placebo-Controlled Trial to Investigate Efficacy and Safety of Degarelix in Men with Lower Urinary Tract Symptoms (LUTS) Associated with Benign Prostatic Hyperplasia”
- 94) Warner Chilcott 2010: PR 01209”A Randomized Placebo-controlled, Double-Blind, Parallel Design Phase 3 Study to Assess the Safety and Efficacy of WC3043 Tablets in Male Subjects with Erectile Dysfunction”
- 95) Warner Chilcott 2010: PR01409 “An Open-Label Phase 3 Study to Evaluate the Long-Term Safety and Efficacy of WC3043 Tablets in Male Subjects with Erectile Dysfunction”
- 96) Predictive Bioscience 2010: PR-001 “Hematuria Evaluation Trial Device Trial”
- 97) Predictive Bioscience 2010: PR-002 “Hematuria Evaluation Trial Device Trial”
- 98) Serenity Pharmaceuticals 2010: “A Phase III Randomized, Double Blind, Placebo Control, Multi-Center Study to Investigate the Efficacy and Safety of SER120 Nasal Spray Formulation in Patients with Nocturia”
- 99) RTOG (Radiation therapy oncology group) 2010: Phase II trial.
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Lawrence I. Karsh, M.D.

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