

CURRICULUM VITAE
LAWRENCE I. KARSH, M.D., F.A.C.S. C.P.I.
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Signature: 

Date: 11/22/16

EDUCATION

University of Colorado, 1973

B.A., English, Chemistry, Biology

Chicago Medical School, 1978 M.D.

POST-DOCTORAL TRAINING

University of Colorado School of Medicine, Denver, Colorado

Department of Surgery

Surgeon-in-Chief, Thomas Starzl, M.D.

1978 - 1979 Surgical Intern

1979 - 1980 Surgical Resident

Harvard Medical School, Boston, Massachusetts

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

Director of Research-The Urology Center of Colorado, Denver, Colorado, 1997 to present

Private Practice - The Urology Center of Colorado, Denver, Colorado, 2006 to present

Private Practice - Western Urologic Associates, Wheat Ridge, Colorado, 1999 - 2006

Private Practice - Urology Surgical Associates, Denver, Colorado, 1984 - 1999

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

BOARD CERTIFICATION

Association of Clinical Research Professionals - Certified Principal Investigator, recertified 2013

Association of Clinical Research Professionals - Certified Principal Investigator (CPI), 2011

Re-certified American Board of Urology, 2013 - 2026

Re-certified American Board of Urology, 2003 - 2016

Re-certified American Board of Urology, 1993 - 2006

Fellow-American College of Surgeons, 1987 to Present

American Board of Urology, 1986

National Board of Medical Examiners, 1979

MEDICAL LICENSURE

Colorado, 1979 to Present (#23129)

LANGUAGES

English & Spanish

HOSPITAL AFFILIATIONS

Exempla Lutheran Medical Center

Saint Anthony Hospital

PROFESSIONAL MEMBERSHIPS/ORGANIZATIONS

Society of Basic Urologic Research, Inc., 2013 to present

American Society of Clinical Oncology, (ASCO) 2012 to Present

Association of Clinical Research Professionals, (ACRP) 2011 to Present

Bladder Cancer Advocacy Network, (BCAN) 2010 to present

Radiation Therapy Oncology Group, (RTOG) 2009 to 2014

Society of Urologic Oncology, (SUO) 2010 to Present

Society of Urologic Oncology Clinical Trials Consortium, (SUO-CTC) Board of Directors 2010 to Present

Large Urology Group Practice Association, 2009 to present

Southwest Oncology Group, (SWOG) 2006 to Present

National Cancer Institute Investigator - 2000 to Present

Denver Academy of Surgery, 1988 to Present

American College of Surgeons, 1987 to Present

American Urologic Association, 1985 to Present

SPECIALTY INTERESTS

Clinical Research

Oncology and Oncologic Surgery

Stone Disease

Incontinence

Prostate Disease

ACADEMIC APPOINTMENTS

Department of Surgery, University of Colorado Health Sciences Center, Denver, Colorado

1985 - Present, Assistant Clinical Professor of Surgery/Urology

Department of Surgery, Harvard Medical School, Boston, Massachusetts

1980 - 1984, Clinical Fellow in Surgery

SPECIAL ADVISOR FOR INDUSTRY

Spectrum Pharmaceuticals Advisor

(FDA) Food and Drug Administration, Center for Drug Evaluation and Research (CDER). Oncologic Drugs Advisory Committee (ODAC) Meeting, Silver Spring Maryland, September 14, 2016

ADVISORY BOARD MODERATOR

Xtandi Urology Advisory Board Denver, CO September 18, 2015

Provenge and its use in Community-Based Urology Practice Advisory Board Meeting Co-Moderator
Bryan Mehlhaff, MD Santa Barbara, CA February 7, 2014

Provenge and its use in Community-Based Urology Practice Advisory Board Meeting Co-Moderator
Raoul Concepcion, MD San Francisco, CA October 4, 2013

SCIENTIFIC ADVISORY COMMITTEE

Society of Urologic Oncology Clinical Trials Consortium, (SUO-CTC) Principal Investigator

Janssen/Aragon Pharmaceuticals - A Phase 3 Randomized, Placebo-Controlled, Double-blind Study of JNJ-56021927 plus Androgen Deprivation Therapy (ADT) Versus ADT in Subjects with Low-volume Metastatic Hormone-Sensitive Prostate Cancer (mHSPC). June 2015-present

Astellas Registry Protocol AXA24013 August 2014 to present

Society of Urologic Oncology Clinical Trials Consortium, (SUO-CTC) Principal Investigator

Heat - A Phase 1/2a, Placebo-Controlled, Randomized Study to Evaluate the Safety, Immune Response and Clinical Activity of HS-410 in Patients with High-Risk Non-Muscle Invasive Bladder Cancer Who Have Undergone Transurethral Resection of Bladder Tumor (TURBT) and Received Prior Treatment with Induction Bacillus Calmette-Guérin (BCG).
December 2012-present

Scientific Advisory Board Member Bladder Cancer Advocacy Network, (BCAN) 2010 to present

ADVISORY BOARDS

Amgen 2008 - 2012

Pfizer 2010

Dendreon 2010 to present

Janssen 2011 to present

Sanofi 2015 to present

Astellas 2011 to present

Medivation 2011 to present

Bayer 2011 to present

Genomic Health 2013 to present

BN ImmunoTherapeutics 2014 to 2015

Myriad Genetics 2014 to present

SUO Clinical Trials Consortium - Bladder Cancer Sub-Committee 2009 to present

Tolmar 2015

Ferring 2016

Abbvie 2016

AWARDS

Brownes Resident, Urodynamic Prize, "Urology Times", Vol. 10, No.4, April 1982

EDITORIAL BOARD- Journal Publications

Bladder Cancer 2014 to present

Urologists in Cancer Care - 2011 to present

AUDIO DIGEST

Audio-Digest Oncology Program Title: Newly Diagnosed Advanced and Metastatic Prostate Cancer

Lecture (s) Published: "Androgen Biosynthesis Inhibitors vs Androgen Receptor Antagonists for Prostate Cancer."
Lawrence I. Karsh, MD Volume 06, Issue 13 July 7, 2015, ISSN 2154-4581

Audio-Digest Urology Title: Hormone Therapy for Prostate Cancer

Lecture (s) Published: "Androgen Biosynthesis Inhibitors vs Androgen Receptor."
Lawrence I. Karsh, MD Volume 38, Issue 24 December 21, 2015, ISSN 0271-1338

FACULTY PRESENTATIONS

Live Speaker Faculty Training,

Xandi Speaker Bureau Live Training Meeting Atlanta, GA, January 30, 2016

Live Speaker Faculty Training,

Astellas/Medivation Chicago, IL, October 11, 2014

Screening Committee and WebEx Training,

Astellas/Medivation PRVAIL Slide Deck September 10, 2014

Speaker Faculty Training,

Amgen Xgeva/Prolaris Dallas, TX, June 14-15, 2012

Bladder Cancer Advocacy Network Symposium

"Non-Muscle Invasive Bladder Cancer" Denver, Colorado, September 24, 2011

TUCC Patient Symposium

"Understanding Prostatic Health" Denver, Colorado, April 11, 2011

Speaker Training Instructor,

"Overactive Bladder" Pfizer-Tovias Phoenix, Arizona, January 2011

Cleveland Clinic SUO Clinical Trials Consortium Therapeutic Course

"The Essential Role of 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

TUCC Patient Symposium

"Current Medical and Surgical Therapy for Male Urinary Incontinence" Denver, Colorado, May 20, 2010

SOAR

"Male and Female Incontinence-Courses and Current Therapy" Wheat Ridge, Colorado, February 20, 2010

Large Urology Group Practice Association

"Bone Health in Patients with Metastatic Prostate Cancer" Chicago, Illinois, November 6, 2009

The Urology Center of Colorado

"Good Clinical Practice" Workshop Instructor, Denver, Colorado, March, 2008

The Urology Center of Colorado

"Good Clinical Practice" Workshop Instructor, Denver, Colorado, March, 2007

The Urology Center of Colorado

"Good Clinical Practice" Workshop Instructor, Denver, Colorado, March, 2006

Westin Tabor Center

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

Centura Seniors Program

"Prostate Cancer and Treatment" Denver, Colorado, July, 1998

St. Anthony Family Resident Program

"Treating Erectile Dysfunction" Denver, Colorado, June, 1998

Primary Care Symposium

"BPH - Historical Review and Management" Denver, Colorado, April, 1998

Primary Care Education Series

“Current Perspectives in Management of Benign Prostatic Hyperplasia” Denver, Colorado, November, 1997

Primary Care Perspective Symposium

“BPH and Other Urologic Disorders” Denver, Colorado, November, 1996

Primary Care Education Series

“Diagnosis and Management of Erectile Dysfunction” Denver, Colorado, November, 1996

Phoenix Urological Society

“Continent Urinary Diversion” Phoenix, Arizona, September, 1988

Kansas City Urological Society

“Continent Urinary Diversion” Kansas City, Kansas, May, 1988

TELEVISION & VIDEO

9News Colorado’s News Leaders “Firefighter’s Cancer in Remission after Experimental Drug.” November 8, 2016

Grand Rounds in Urology Video “Biosynthesis Inhibitors or Anti-Androgens: Which One should I Choose”? August, 2016

Grand Rounds in Urology Video “The Future of Clinical Research in Private Practice: Alive or Dead”? International Prostate Cancer Update Vail, Colorado, January 23, 2016

Labroots Vitural Event “How do I Choose? “Androgen Biosynthesis Inhibitor, Androgen Receptor Antagonist, or both for treatment of mCRPC?” September 30, 2015

Astellas/Medivation Live Broadcast for “Xtandi Continuing Care for your Patients with Metastatic CRPC.” Burbank, California, October 8, 2014

Patient Power, “Immediate Benefits of Participating in Prostate Cancer Research.”

<http://www.patientpower.info/video/immediate-benefits-of-participating-in-prostate-cancer-research?autoplay=1>

Produced in association with The Prostate Net, July 15, 2013

OncLive Prostate Cancer Video, “Managing Metastatic Castration Resistant Prostate Cancer.”

San Diego, California, May 5, 2013

Vasectomy Panel “Exercise Induced Increases in Plasma Calcium Concentration Occur Equally in Normal and Thyroidectomized Humans.” Boston, Massachusetts, July, 1982

FACULTY INSTRUCTOR

PIM Postgraduate Institute for Medicine 21th Scottsdale Prostate Cancer Symposium 2016

Androgen Biosynthesis Inhibitors/Androgen Receptor Antagonists/Combination Therapy March 12, 2016

Bone Targeting Agents March 12, 2016

PIM Postgraduate Institute for Medicine 20th Scottsdale Prostate Cancer Symposium 2015

Biosynthesis Inhibitors or Anti-Androgens March 5, 2015

Improving Urine Control after Prostatectomy March 8, 2015

POST GRADUATE COURSES

AUA 2016 San Diego

ARS091PG: Novel Agents and Concepts in the Management of Hormone Naïve and Castration Resistant Prostate Cancer

San Diego, California, May 10, 2016

AUA 2015 Course Webcast

093PG: Sequencing Novel Agents and Understanding Novel Concepts in Hormone Naïve and Castration Resistant Prostate Cancer

www.auanet.org, May 15, 2015

PODIUM PRESENTATIONS

AUA 2016 San Diego

“Integrated Results of Two Multicenter, Randomized, Placebo Controlled, Double Blind, Phase 3 Trials (SPI-611/612) of Single-Dose Intravesical Apaziquone Immediately Following Resection in Patients With Non-Muscle Invasive Bladder Cancer”

PD11-07 AUA San Diego Convention Center, San Diego, California, May 7, 2016.

AUA 2016 San Diego

“Renal Function before and After Cytoreductive Nephrectomy in A Phase 3 Randomized Clinical Trial.” PD04-02 AUA San Diego Convention Center, San Diego, California, May 6, 2016

International Prostate Cancer Update

“The Future of Clinical Research in Private Practice: Alive or Dead? Cascade Conference Center Vail, Colorado, January 23, 2016

SUO Society of Urologic Oncology

“Denosumab and Bone-Metastasis-Free Survival in Men with Castration-Resistant Prostate Cancer, Results of a Phase 3 Randomized Placebo-Controlled Trial.” Maryland, November 30-December 2, 2011

International Prostatic Cancer Update

“A Phase III Randomized Trial of Denosumab vs. Zoledronic Acid in Patients with Bone Metastases from Castration Resistant Prostate Cancer.” Vail, Colorado January 27-29, 2011

SUO Clinical Trials Consortium-Bladder Cancer Sub-Committee

“Bladder Cancer Statistics Update-National Institutes of Health.” Bethesda, Maryland, December 9, 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

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, Pennsylvania, September 25, 2010

ASCO Annual Meeting

Prevalence and Consequences of Bone Metastases and Skeletal-Related Events (SREs) Chicago IL June 4-8 2010

Colorado Chapter of the American College of Surgeons

“Continent Urinary Diversion” Colorado Springs, Colorado, May, 1988

New England Section AUA

“Spermatogenesis-It’s Effect upon the Immune Rejection of Intratesticular Grafts” Bermuda, September, 1983

Society for Bone and Mineral Metabolism

“Exercise Induced Increases in Plasma Calcium Concentration” San Francisco, California, June, 1982

New England Section AUA

“Renal Artery Aneurysms” Palm Beach, Florida, September, 1981

DISCUSSANTS PANEL

2016 LUGPA CME PRESENTATION “Systemic Immunotherapy Bladder” Chicago, Illinois, November 3, 2016

2015 LUGPA CME COURSE “Testosterone Supplementation: Specific Recommendations Therapy and No, The Recent Warnings are not Justified-We Are Not Overtreating” Chicago, Illinois, November 5, 2015

2015 LUGPA CME COURSE CRPC: “What to Do With Progression after Abi or Enza”? Chicago, Illinois, November 5, 2015

MODERATOR TUCC VISITING PROFESSOR LECTURE PROGRAM

Colin Dinney M.D.

Emerging Therapy for BCG Unresponsive Bladder Cancer July 15, 2016

Denise Bickel PhD, MSW, LCSW

“Facilitating Crucial Conversations & Palliative Care” June 10, 2016

David Mois Albala M.D.

“Genomic Markers” April 15, 2016

Bryan Mehlhaff, M.D.

“Xofigo (Radium Ra 223 dichloride) for the Treatment of Castration-Resistant Prostate Cancer with Symptomatic Bone Metastases” October 16, 2015

Eric Klein, M.D.

“A Genomic Approach to Active Surveillance: a Step toward Precision Medicine” April 30, 2015

Stephen J Freedland, M.D.

“Obesity and Prostate Cancer” February 20, 2015

Evan Yu, M.D.

“Immunology in GU Oncology” February 6, 2015

Michael Brawer, M.D.

“Prolaris Cell Cycle Progression Biomarker” November 21, 2014

Neal A. Shore, M.D.

“New Biomarkers, Prolaris” July 18, 2014

Peter Carroll, M.D. MPH

“Prostate Cancer – To Treat or Not to Treat”? June 2, 2014

Leonard G. Gomella, M.D., F.A.C.S.

“Beyond PSA: Prostate Cancer Biomarkers” March 28, 2014

Carsten Goessl M.D.

“A Randomized, Double-Blind, Phase 3 Efficacy Trial of PROSTVAC-V/F ± GM-CSF in Men with Asymptomatic or Minimally Symptomatic Metastatic, Castrate-Resistant Prostate Cancer” December 13, 2013

Judd Moul, M.D.

“Prostate Cancer- Early Detection- Controversy 2013” November 22, 2013

Guillermo Davila, M.D.

“Female Urology” September 27, 2013

Robert E. Donohue, M.D.

“Low Grade, Low Volume Carcinoma of the Prostate is Treatment Necessary? Whom to treat?” August 18, 2013

Charles Drake, M.D. PhD

“Metastatic Castration Resistant Prostate Cancer: Emerging Therapeutics of Immunotherapy” July 26, 2013

Dan Theodorescu, M.D. PhD

“Individualized Therapy in Bladder Cancer” May 17, 2013

Claus G. Roehrborn, M.D.

“Medical Therapy for Male LUTS and BPH” April 19, 2013

William Shipley, M.D.

“Update of Selective Bladder Preserving Approaches” December 14, 2012

Seth Lerner, M.D.

“Update on Muscle Invasive Bladder Cancer” September 21, 2012

Paul Lange, M.D.

“Local Control in Prostate Cancer” August 31, 2012

Thomas Keane, M.D.

“Androgen Deprivation Therapy” June 29, 2012

Marshall S. Lucia, M.D.

“The Potential Impact of 5-ARI’s on Prostate Cancer-A Pathologist’s Perspective” April 26, 2012

Paul K. Sand, M.D.

“Use of Adjuvant Grafts in Reconstructive Pelvic Surgery” January 20, 2012

Nicolas J. Vogelzang, M.D.

“Target Therapy for Metastatic Prostate Cancer” January 09, 2011

Edward M. Messing, M.D.

“Bladder Cancer 2011: Clinical Challenges and Opportunities Raising the Bar” November 18, 2011

Year 2010

Steve Wilson, M.D., November 29, 2010

Larry I. Lipschultz, M.D., November 19, 2010

John Ning, M.D., October 28, 2010

David R. Staskin, M.D., September 30, 2010

Donald L. Lamb, M.D., July 22, 2010
Paul D. Maroni, M.D., June 18, 2010
Neal A. Shore, M.D., May 27, 2010
Frans M. Debruyne M.D., May 4, 2010
Laurence A. Levine, M.D., April 22, 2010
Gerald L. Andriole, M.D., March 26, 2010
Ronald Walls, M.D., February 19, 2010
Shonee Lesh, M.S., January 28, 2010

INDUSTRY SPONSORED LECTURES

LUGPA Xtandi Symposium

“Continuing Care for your Patients with Metastatic CRPC” Chicago, IL, November 4, 2016

Janssen Biotech, Inc

“Rio Grande Urology APC Champion Program, Uro 2016 Zytiga Case Deck Lecture Format” Princeton, NJ, October 21, 2016

AUA South Central Section

Xtandi (enzalutamide) “Capsules Symposium Program: Continuing Care for your Patients with Metastatic CRPC”
Colorado Springs, CO, September 29, 2016

Janssen Biotech, Inc

“Rio Grande Urology APC Champion Program, Uro 2016 Zytiga Case Deck Lecture Format” Tulsa, OK, August 5, 2016

UROGPO Rio Grande Urology APC Champion Program

Xtandi (enzalutamide) “Capsules in the Urology Practice: Continuing Care for your Patients with Metastatic CRPC”
El Paso, TX, July 30, 2016

UROGPO Rio Grande Urology APC Champion Program

Xtandi (enzalutamide) “Capsules in the Urology Practice: Continuing Care for your Patients with Metastatic CRPC”
Louisville, KY, January 9, 2016

LUGPA

Xtandi (enzalutamide)

“Capsules in the Urology Practice: Continuing Care for your Patients with Metastatic CRPC” Chicago, IL, November 6, 2015

Urology Associates

Zytiga (Abiraterone acetate)

“Practical Approach to the Management of Metastatic Castrate Resistant Prostatic Cancer (mCRPC)” Fresno, CA,
December 11, 2014

VA Hospital

Zytiga (abiraterone acetate)

“Practical Approach to the Management of Metastatic Castrate Resistant Prostatic Cancer (mCRPC)” Fresno, CA,
December 11, 2014

Lutheran Medical Radiation Oncology Group

Xofigo (Radium 223 dichloride) “For the Treatment of Castration-Resistant Prostate Cancer with Symptomatic Bone Metastasis”
Golden, CO, November 11, 2014

AUA South Central Section Annual Meeting

Xtandi (enzalutamide) Capsules in the Urology Practice: “Continuing Care for Your Patients with Metastatic CRPC” Palm Springs,
CA, October 9, 2014

29th International Prostate Cancer Update

XTANDI (enzalutamide) Capsules in the Urology Practice: “Continuing Care for Your Patients with Metastatic CRPC” Vail, CO,
February 21, 2014

Genesis Healthcare

Xofigo (Radium 223 dichloride) “For the Treatment of Castration-Resistant Prostate Cancer with Symptomatic Bone Metastasis”
San Diego, CA, August 8, 2014

SUO

Xtandi (enzalutamide) "An Option for Continuing the Care of Patients with mCRPC in the Urology Practice" Bethesda, MD
December 6, 2013

LUGPA

Xofigo (radium 223 dichloride) "For the Treatment of Castration-Resistant Prostate Cancer with Symptomatic Bone Metastasis"
Chicago, IL, November 7, 2013

AUA Western Section

Xofigo (radium 223 dichloride) "For the Treatment of Castration-Resistant Prostate Cancer with Symptomatic Bone Metastasis"
Monterey, CA, November 4, 2013

AUA South Central Section

Xtandi (enzalutamide) "An Option for Continuing the Care of Patients with mCRPC in the Urology Practice" Chicago, IL,
September 19, 2013

Idaho Falls Urology

Zytiga (abiraterone Acetate) "Introducing a New Option for Patients with MCRPC before Chemotherapy" Idaho Falls, ID,
July 11, 2013

Fort Collins Urology

Xtandi (enzalutamide) "An Option for Continuing the Care of Patients with mCRPC in the Urology Practice" Fort Collins, CO,
June 26, 2013

Rocky Mountain Urologic Society

Xtandi (enzalutamide) "An Option for Continuing the Care of Patients with mCRPC in the Urology Practice" Denver, CO,
April 13, 2013

AUA South Central Section

Xgeva (Denosumab) "Decision Points: Practical Considerations for Bone Health in Patients with Prostatic Cancer"
Colorado Springs, CO, October 27, 2012

Arizona Urological Society

"Xgeva (Denosumab) and Prostatic Cancer-Identifying Bone Metastases and Skeletal Related Events" Sedona, Arizona,
March 3, 2012

Winter Urological Forum

"Xgeva (Denosumab) and Prostatic Cancer-Identifying Bone Metastases and Skeletal Related Events" Snowmass, Colorado,
January 20, 2012

Scottsdale Urology Group

"Xgeva (Denosumab) and Prostatic Cancer-Identifying Bone Metastases and Skeletal Related Events" Scottsdale, Arizona,
October 19, 2011

TUCC Foundation Blue Shoe Run

"Xgeva (Denosumab) and Prostatic Cancer-Identifying Bone Metastases and Skeletal Related Events" Denver, Colorado,
September 7, 2011

AUA Western Section

"Xgeva (Denosumab) and Prostatic Cancer-Identifying Bone Metastases and Skeletal Related Events" Vancouver, British
Columbia, August 22, 2011

POSTERS**Number Needed to Treat to Avoid a Clinical Progression Event: Comparison of Enzalutamide Versus**

Bicalutamide in Patients with Metastatic Castration-Resistant Prostate Cancer. Raoul S. Concepcion,¹ David F.

Penson,² Lawrence Karsh,³ Hongbo Yang,⁴ Neil M. Schultz,⁵ Bruce A. Brown,⁵ Arie Barlev,⁶ and Scott C. Flanders⁵

¹Urology Associates, Nashville, TN, USA; ²Vanderbilt University Medical Center, Nashville, TN, USA; ³The Urology Center of Colorado, Denver, CO, USA; ⁴Analysis Group, Inc., Boston, MA, USA; ⁵Astellas Pharma Global Development, Inc., Northbrook, IL, USA; ⁶Medivation, Inc. (Medivation was acquired by Pfizer, Inc. in September 2016), San Francisco, CA, USA. 17th Annual Meeting of the Society of Urologic Oncology, November 30–December 2, 2016, San Antonio, Texas.

Immunogenicity Of Sipuleucel-T In Abiraterone/Enzalutamide Sensitive and Resistant Metastatic Castrate-Resistant Prostate Cancer. Karsh LI1*, Fong L2, Petrylak D3, Quinn D4, Drake CG5,6, Campogan D7, Vu T7, Sheikh N7, Chang N7, Small EJ2. 1The Urology Center of Colorado, Colorado, USA; 2UCSF Helen Diller Family Comprehensive Cancer Center, University of California, San Francisco, USA; 3Smilow Cancer Center, Yale University, New Haven, USA; 4University of Southern California Norris Comprehensive Cancer, Los Angeles, USA; 5Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, Baltimore, USA; 6Brady Urological Institute, Baltimore, USA; 7Dendreon Pharmaceuticals, Inc., Seattle, USA. Presented at the Western Section of the American Urological Society 2016, Kauai, Hawaii, October 23–28, 2016.

Neo/adjuvant ADT to EBRT: Final Results of the Randomized Phase 2 Trial of the Oral GnRH Antagonist, TAK-385 (Relugolix) and Degarelix in Patients with Prostate Cancer. David P. Dearnaley,1Daniel R. Saltzstein,2John E. Sylvester,3Lawrence Karsh,4Bryan A. Mehlhaff,5Christopher Pieczonka,6James L. Bailen,7David B. MacLean,8ZhanYe,8 H el ene M. Faessel,8 Huamao Mark Lin, and Neal D. Shore9. 1The Institute of Cancer Research/Royal Marsden Hospital, Sutton, Surrey, UK; 2Urology San Antonio, San Antonio, TX, USA; 321stCentury Oncology, Bradenton, FL, USA;4The Urology Center of Colorado, Denver, CO, USA; 5Oregon Urology, Springfield, OR, USA;6Associated Medical Professionals of NY, Syracuse, NY, USA; 7First Urology, Jeffersonville, IN, USA; 8Millennium Pharmaceuticals, Inc., Cambridge, MA, USA, a wholly owned subsidiary of Takeda Pharmaceutical Company Limited;9Carolina Urologic Research Center, Myrtle Beach, SC, USA. Poster presented at the 2016 European Society for Medical Oncology in Copenhagen, Denmark, October 7–11, 2016

The 4KSCORE Test Predicts High Grade Prostate Cancer on Biopsy at PSA Levels<4NG/ML. Lawrence Karsh MD1, Stephen Zappala MD2, Mohit Mathur MD, PhD3, Jay Newmark MD3, Grannum Sant MD3 and Mitchell Steiner MD3. 1The Urology Center of Colorado; 2Andover Urology; 3OPKO. Presented by: Lawrence Karsh. South Central Section AUA 2016 Colorado Springs, CO September 29, 2016.

A Genomic Classifier Impacts Adjuvant Treatment Decision-Making among Patients with High-Risk Pathology at Radical Prostatectomy: Results from the Multicenter Prospective PRO-IMPACT Study. John L. Gore1, Marguerite du Plessis2, Maria Santiago-Jim enez2, Kasra Yousefi2, Darby Thompson3, Mark Bandyk4, Fernando Bianco5, Gordon Brown6, David Chen7, William Clark8, Michael Franks9, Lawrence Karsh10, Adam Kibel11, HyungKim12, Brian Lane13, YairLotan14, William Lowrance15, MurugesanManoharan16, Paul Maroni17, Scott Perrapato18, Paul Sieber19, Edouard Trabulsi20, Robert Waterhouse21, Elai Davicioni2, Daniel Lin. SUO CTC Society of Urologic Oncology Clinical Trials Consortium, Inc. May 26, 2016.

Integrated Results of Two Multicenter, Randomized, Placebo Controlled, Double Blind, Phase 3 Trials (SPI-611/612) of Single-Dose Intravesical Apaziquone Immediately Following Resection in Patients With Non-Muscle Invasive Bladder Cancer. Lawrence Karsh, Denver, CO, Neal Shore, Myrtle Beach, SC, Daniel Saltzstein, San Antonio, TX, Gajanan Bhat, Guru Reddy, Lee F. Allen, Irvine, CA, Mark Soloway, Aventura, FL, PD11-07 AUA San Diego Convention Center, San Diego, California, May 7, 2016.

Improved Efficacy of Adjuvant, Single Dose Intravesical Apaziquone by Timing Post-Resection in Two Double-Blind, Randomized, Placebo-Controlled Phase 3 Studies in Non-Muscle Invasive Bladder Cancer. Fred Witjes, Nijmegen, Netherlands, Lawrence Karsh, Denver, CO, Mark Soloway, Aventura, FL, Gajanan Bhat, Guru Reddy, Allen Yang, Lee F. Allen, Irvine, CA, Neal Shore, Myrtle Beach, SC, MP13-07 AUA San Diego Convention Center, San Diego, California, May 6, 2016.

Renal Function before and After Cytoreductive Nephrectomy in A Phase 3 Randomized Clinical Trial. Erik N. Mayer, William T. Lowrance, Salt Lake City, UT, Robert Uzzo, Philadelphia, PA, Christopher Wood, Houston, TX, Alexander Kutikov, Marc Smaldone, Philadelphia, PA, Jason Gee, Burlington, MA, William Huang, New York, NY, Thomas Gardner, Indianapolis, IN, Gennady Bratslavsky, Syracuse, NY, Jeff Holzbeierlein, Kansas City, MO, Lawrence Karsh, Denver, CO, Viraj Master, Atlanta, GA, Neal Shore, Myrtle Beach, SC, Brian Lane, Grand Rapids, MI, PD04-02 San Diego Convention Center, San Diego, California, AUA May 6, 2016.

Randomized Phase 2 Study Evaluating Optimal Sequencing of Sipuleucel-T and Androgen Deprivation Therapy (STAND) in Biochemically Recurrent Prostate Cancer: Preliminary Clinical Outcomes. Adam Kibel, Charles Drake, George Adams, Lawrence Karsh, Aymen Elfiky, Neal Shore, Nicholas Vogelzang, John Corman, Robert Tyler, Johnathan Maher, Todd DeVries, Nadeem Sheikh, Emmanuel Antonarakis, Presented at American Association of Genitourinary Surgeons (AAGUS) New Orleans, LA May 19, 2015 10:30 AM-12:30 PM Abstract: MP87-15. AUA

TERRAIN Trial: Prostate-specific Antigen Kinetics and Quality of Life Results of Enzalutamide Versus Bicalutamide in Metastatic Castration-Resistant Prostate Cancer. Neal Shore, Axel Heidenreich, Arnauld Villers, Laurence Klotz, Maha Hussain, Lawrence Karsh, Steve van Os, Fong Wang, David Forer, Simon Chowdhury, Robert D. Siemens. Presented at American Association of Genitourinary Surgeons (AAGUS) New Orleans, LA May 17, 2015 10:45 AM-11:41 AM Abstract: PII-LBA4

Phase II Trial of Intravesical Adenoviral Mediated Interferon- α Gene Therapy with the Excipient Syn3 (rAd-IFN α /Syn3 in Patients with BCG Refractory or Relapsing High Grade (HG) Non Muscle Invasive Bladder Cancer (NMIBC). Daniel Canter, Stephen Boorjian, Kenneth Ogan, Neal Shore, Trinity Bivalacqua, Bernard Bochner, Tracy Downs, Leonard Gomella, Robert Grubb III, Brant Inman, Ashish Kamat, Larry Karsh, Tracey Krupski, Seth Lerner, Yair Lotan, Matthew Milowsky, Mark Schoenberg, Robert Svatek, Michael Woods, Colin Dinney. Presented at American Association of Genitourinary Surgeons (AAGUS) New Orleans, LA May 16, 2015 3:30 PM-5:30 PM Abstract: PD17-06

PUBLICATIONS & ABSTRACTS

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200. **Spectrum Pharmaceutical** 9/2015: SPI-EOQ-13-305 “A Multicenter, Multi-Arm, Randomized, Multi-Dose, Placebo-Controlled, Double-Blind, Phase 3 Study of Intravesical Apaziquone (EOquin®) as a Surgical Adjuvant in the Immediate Postoperative Period in Patients Undergoing Transurethral Resection for Non-Muscle Invasive Bladder Cancer.”
199. **Janssen/Aragon Pharmaceuticals** 9/2015: PCR 3003 “A Randomized, Double-blind, Placebo-controlled Phase 3 Study of JNJ-56021927 in Subjects with High-risk, Localized or Locally Advanced Prostate Cancer Receiving Treatment with Primary Radiation Therapy.”
198. **Bayer** 9/2015: BAY88-823-15396 **Radium** “A Phase III Randomized, Double-Blind, Placebo-Controlled Trial of Radium-223 Dichloride in Combination with Abiraterone Acetate and Prednisone/Prednisolone in the Treatment of Asymptomatic or Mildly Symptomatic Chemotherapy-Naïve Subjects with Bone Predominant Metastatic Castration-Resistant Prostate Cancer (CRPC).”
197. **NeoGenomics Laboratories** 8/2015: VI “Predicting Prostatectomy Results using Blood and Urine Biomarkers.”
196. **Tokai Pharmaceuticals** 8/2015: “Armor3-Sv “A Phase 3, Randomized, Open Label, Multicenter, Controlled Study of Galeterone Compared To Enzalutamide In Men Expressing Androgen Receptor Splice Variant-7 Mrna (Ar-V7) Metastatic (M1) Castrate Resistant Prostate Cancer (Crpc).”
195. **Janssen/Aragon Pharmaceuticals** 6/2015: PCR 3002 “A Phase 3 Randomized, Placebo-Controlled, Double-blind Study of JNJ-56021927 plus Androgen Deprivation Therapy (ADT) Versus ADT in Subjects with Low-volume Metastatic Hormone-Sensitive Prostate Cancer (mHSPC).”

194. **Bayer** 5/2015: ODM17777 “A Randomized, Double-Blind, Placebo Controlled Phase III Study of ODM-201 Versus Placebo in Combination with Standard Therapy (Androgen Deprivation Therapy (ADT) with or without a Docetaxel Containing Chemotherapy Regimen) for Patients with Newly Diagnosed Metastatic Castration Sensitive Prostate Cancer (mCSPC).”
193. **Orion Pharma** 3/2015: 3104007 **ARAMIS** “A Multinational, Randomized, Double-Blind, Placebo-Controlled, Phase 3, Efficacy and Safety Study of Odm-201 in Men with High-Risk Non-Metastatic Castration-Resistant Prostate Cancer.”
192. **University of Colorado Anschutz Medical Campus CU Optics** 3/2015: “Performance Evaluation of The Claricore Optical Biopsy System Designed by Precision Biopsy for Prostate Cancer Diagnosis.”
191. **Astellas TRUMPET** 03/2015: ONC-MA-1004 “A Prospective Observational Cohort Study of Patients with Castration-Resistant Prostate Cancer (CRPC) in the United States.”
190. **Janssen /Aragon Pharmaceuticals** 2/2015: METS PCR3001 “A Phase 3 Randomized, Placebo-Controlled Double-Blind Study of JNJ-56021927 in Combination with Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone in Subjects with Chemotherapy-Naive Metastatic Castration-Resistant Prostate Cancer (mCRPC).”
189. **Medivation Inc, EMBARK** 12/2014: “A Phase Three, Randomized, Efficacy and Safety Study of Enzalutamide Plus Leuprolide, Enzalutamide Monotherapy, and Placebo Plus Leuprolide in Men with High-Risk Nonmetastatic Prostate Cancer Progressing after Definitive Therapy.”
188. **Mundipharma Research Limited** 10/2014: “A Phase 2 Randomized, Double-Blind, Placebo Controlled, Study of MR901 in Patients with Moderate to Severe Lower Urinary Tract Symptoms (LUTS) Due to Benign Prostatic Hyperplasia (BPH).”
187. **Genomic Health Inc.** 9/2014: 14-001 “Genomic Markers in Transitional Cell Cancer Of The Bladder, Renal Pelvis And Ureter: Sample Acquisition For Methods Development And Discovery.”
186. **Janssen/SPARTAN** 9/2014: ARN-509 “Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Study of ARN-509 in Men with Non-Metastatic (M0) Castration-Resistant Prostate Cancer.”
185. **GenomeDx Biosciences** Decipher 7/2014: “Validation of a Genomic Classifier that Predicts Metastasis Following Radical Prostatectomy in an At Risk Patient Population.”
184. **Auxilium** 6/2014: 810 “Long-Term Safety, Curvature Deformity Characterization, and Immunogenicity Over Time in Subjects Previously Treated with aa4500 for Peyronie’s Disease in Studies AUX-CC-802, AUX-CC-803, AUX-CC-804, AND AUX-CC-806.”
183. **Takeda** 5/2014: C27003 “A Phase 2, Randomized, Open-Label, Parallel Group Study Evaluating the Safety and Efficacy of TAK-385, an Oral Gonadotropin-Releasing Hormone (GnRH) Antagonist, for Patients With Localized Prostate Cancer Requiring Neoadjuvant and Adjuvant Androgen Deprivation Therapy With External Beam Radiation Therapy (EBRT).”
182. **Astellas** 05/2014: 178-CL-101/102 **SYNERGY** “A Randomized, Double-Blind, Parallel-Group, Active-Controlled, Multi-Center Study to Evaluate the Long-Term Safety and Efficacy of Combination of Solifenacin Succinate With Mirabegron Compared to Solifenacin Succinate and Mirabegron Monotherapy in Subjects With Overactive Bladder.”
181. **Takeda** 4/2014: C27002 “A Phase 2, Randomized, Open-label, Parallel Group Study to Evaluate the Safety and Efficacy of the Oral GnRH Antagonist TAK-385, Together With a Leuprorelin Observational Cohort, in Patients With Prostate Cancer.”
180. **PASCUAL** (Prostate Assay Specific Clinical Utility at Launch Study) 4/2014: “A Randomized, Controlled Prospective Study to Track the Clinical Utility of an Epigenetic Assay, ConfirmMDx[®] for Prostate Cancer, in U.S. Urologic Practices for Histologically Cancer-Negative Patient Management.”
179. **Minomic International Ltd** 4/2014: “MiStar[™] ELISA Pilot Study (Pilot Study) for Prostate Cancer.”
178. **Genomic Health Inc.** 4/2014: Oncotype DX 09-023 “A Prospective Multicenter Observational Trial to Assess Persistence on Active Surveillance When Using the Oncotype DX Prostate Cancer Assay.”
177. **Pfizer** 02/2014: A4061070 “Metastatic Renal Cell Cancer Registry (MaRCC).”

176. **Myriad** 2/2014: “A Feasibility Study to Determine Whether Bladder Cancer can be Detected by Mutational Screening of DNA Markers in Urine.”
175. **Evidera** 2/2014: A2-8796-007 “Psychometric Evaluation of the Hypogonadism Impact of Symptoms Questionnaire (HIS-Q).”
174. **Sophiris** 1/2014: PRX302-3-01 “A Randomized, Double-Blind, Vehicle-Controlled, Multicenter Safety and Efficacy Study of a Single Intraprostatic Treatment of PRX302 for Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia (The PLUS 1 Trial).”
173. **Sequoia** 1/2014: SQ-SH171 “Phase 1 Dose-Escalation Study of the Safety and Immunogenicity of Fimch, an Escherichia Coli Pilus Vaccine, With and Without Adjuvant, in Healthy Adult Women with and without a history of Recurrent Urinary Tract Infections.”
172. **Astellas** 12/2013: Synergy 178-CL-101 “A Randomized, Double-Blind, Parallel-Group, Active-Controlled, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Combination of Solifenacin Succinate With Mirabegron Compared to Solifenacin Succinate and Mirabegron Monotherapy in Subjects With Overactive Bladder.”
171. **Evidera** 9/2013: “Qualitative Research on Patients Experience of Androgen Deprivation Therapy ADT.”
170. **Warner Chilcott** 8/2013 “A study to assess the Safety and Efficacy of Udenafil in Men with Lower Urinary Tract Symptoms (LUTS) Secondary to Benign Prostatic Hyperplasia (BPH).”
169. **Neogenomics Laboratories** 07/2013: “Validation of an SVM Derived, Four-gene Signature Test in Blood and Urine for the Early Detection of Prostate Cancer.”
168. **Aquinox Pharmaceuticals Inc.** 6/2013: AQX-1125 “A Phase 2 Study to Evaluate the Efficacy and Safety of AQX-1125 in Subjects with Interstitial Cystitis/Bladder Pain Syndrome Mediated by the Src Homology-2-Domain-Containing Inositol 5' Phosphatase [SHIP1] Pathway.”
167. **Telomedix**: 5/2013: “Phase II Pilot Study with TMX-101 in Patients with Carcinoma In Situ (CIS) Bladder Cancer.”
166. **Dendreon** 3/2013: P11-4 “Immune Monitoring Protocol in Men with Prostate Cancer Enrolled in a Clinical Trial of Sipuleucel-T (PRIME).”
165. **Amgen** 2/2013: 20101102 “Osteonecrosis of the Jaw (ONJ) Case Registry.”
164. **RTOG** 1/2013: 926 “A Phase II Protocol For Patients With Stage T1 Bladder Cancer To Evaluate Selective Bladder Preserving Treatment By Radiation Therapy Concurrent With Cisplatin Chemotherapy Following A Thorough Transurethral Surgical Re-Staging.”
163. **Auxillium** 1/2013: UBC-A13183 “Evaluating the Reproducibility of the Peyronie’s Disease Questionnaire (PDQ).”
162. **OPKO** 12/2012: “The OPKO Diagnostics 4Kscore™ as a Predictor of Prostate Cancer Prior to Biopsy.”
161. **Heat** 12/2012: HS410-101 “A Phase 1/2a, Placebo-Controlled, Randomized Study to Evaluate the Safety, Immune Response and Clinical Activity of HS-410 in Patients with High-Risk Non-Muscle Invasive Bladder Cancer Who Have Undergone Transurethral Resection of Bladder Tumor (TURBT) and Received Prior Treatment with Induction Bacillus Calmette–Guérin (BCG).”
160. **FKD** 12/2012: rAd-IFN-CS-002 “A Phase II, Randomized, Open Label, Parallel Arm Study to Evaluate the Safety and Efficacy of rAd-IFN/Syn3 Following Intravesical Administration in Subjects with High Grade, BCG Refractory, Relapsed or Resistant Non-Muscle Invasive Bladder Cancer (NMIBC).”
159. **Dendreon** 12/2012: P12-2 “A Randomized, Open-label, Phase 2 Study of Sipuleucel-T, With Concurrent Versus Sequential Administration of Enzalutamide in Men with Metastatic Castrate Resistant Prostate Cancer.”
158. **Dendreon** 12/2012: P12-1 “A Study to Evaluate Characteristics Predictive of a Positive Imaging Study for distant Metastases in Patients with Castration-Resistant Prostate Cancer.”
157. **Augmenix** 12/2012: AGX-11-001-US “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 Study.”
156. **Argos** 11/2012: “An International Phase 3 Randomized Trial of Autologous Dendritic Cell Immunotherapy (AGS-

- 003) Plus Standard Treatment of Advanced Renal Cell Carcinoma (ADAPT).”
155. **Eli Lilly & Co.** 9/2012: “A Randomized, Double-Blind, Placebo-Controlled, Proof-of-Concept Study to Explore the Impact of Testosterone Solution 2% on Symptoms of Ejaculatory Dysfunction in Men with Testosterone Deficiency.”
 154. **Medivation** 8/2012: STRIVE “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.”
 153. **BNIT** 8/2012: “A Randomized, Double-blind, Phase 3 Efficacy Trial of PROSTVAC ± GM-CSF in Men With Asymptomatic or Minimally Symptomatic Metastatic, Castrate-Resistant Prostate Cancer.”
 152. **Auxilium** 8/2012: “A Phase 3, Open-Label Study of the Safety and Effectiveness of AA4500 Administered Twice per Treatment Cycle for Up to Four Treatment Cycles (2 x 4) in Men with Peyronie’s Disease.”
 151. **Endo Pharmaceuticals** 7/2012: ARADES EXTENSION “Safety and Tolerability of ODM-201 in Patients with Castrate Resistant Prostate Cancer: Open, Non-Randomized, Uncontrolled, Multicenter, Extension Study to Study 3104001/EN3386-202.”
 150. **Myriad Genetic Laboratories, Inc.** 7/2012: “Assessment of a Cell Cycle Gene Expression Assay in Biopsies from Patients with Newly-Diagnosed Prostate Adenocarcinoma.”
 149. **Endo Pharmaceuticals** 6/2012: ARADES “Safety and Pharmacokinetics of ODM-201 in Patients with Castrate Resistant Prostate Cancer: Open, Non-Randomized, Uncontrolled, Multicenter, Multiple Dose Escalation Study with A Randomized Phase II Expansion Component.”
 148. **Nymox** 6/2012: NX03-0040 “Phase 2 Multicenter Prospective Open Label 2-Dose Level Clinical Safety and Efficacy Evaluation of Injection of NX-1207 For The Treatment of Low Risk Localized (T1c) Prostate Cancer.”
 147. **Astellas** 5/2012: “A Randomized, Double-Blind, Parallel, Placebo-Controlled, Phase 4, Multi-Center Study To Assess Efficacy And Safety Of Continence Of Subjects After Robotic Assisted Radical Prostatectomy.”
 146. **RTOG** 3/2012: 938 “A Randomized Phase Ii Trial of Hypofractionated Radiotherapy for Favorable Risk Prostate Cancer.”
 145. **Eli Lilly & Co** 3/2012: “An Open-Label, Multicenter, Randomized Phase 2 Study Evaluating the Safety and Efficacy of Docetaxel in Combination With Ramucirumab (IMC-1121B) Drug Product or IMC-18F1 or Without Investigational Therapy as Second-line Therapy in Patients With Locally Advanced or Metastatic Transitional Cell Carcinoma of the Bladder, Urethra, Ureter, or Renal Pelvis Following Disease Progression on First-line Platinum-Based Therapy.”
 144. **Endo Pharmaceuticals** 12/2011: “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 Non-Muscle Invasive Bladder Cancer.”
 143. **Spectrum Pharmaceutical** 10/2011: “A Phase 3 International, Multicenter, Double-Blind, Placebo-Controlled, Randomized Trial Evaluating the Efficacy and Safety of Multiple Instillations of Intravesical Apaziquone versus Placebo in Patients with Low-Intermediate Risk Non-Muscle Invasive Bladder Cancer (NMIBC).”
 142. **Prolaris** 10/2011: “Assessment of a Cell Cycle Gene Expression Assay in Biopsies from Patients with Newly-Diagnosed Prostate Adenocarcinoma.”
 141. **Endo Pharmaceutical Valstar** 9/2011: “A Retrospective Analysis to Evaluate the Effectiveness, Safety and Tolerability of Intravesical Valrubicin for the Treatment of Non-Muscle Invasive Bladder Cancer in Clinical Practice.”
 140. **Dendreon** 9/2011: P11-3 “A Randomized, Open-Label, Phase 2 Trial of Sipuleucel-T With Concurrent Versus Sequential Administration Of Abiraterone Acetate Plus Prednisone In Men With Metastatic Castrate Resistant Prostate Cancer.”
 139. **Dendreon Corporation** 9/2011: N10-1 “A Randomized, Phase 2, Open-Label Study Evaluating DN24-02 as Adjuvant Therapy in Subjects with High Risk HER2+ Urothelial Carcinoma.”
 138. **Dendreon Corporation** 8/2011: P10-3 “A Registry of Sipuleucel-T Therapy in Men with Advanced Prostate

- Cancer.”
137. **Nymox** 8/2011: NX02-0020 “Phase 3 Multicenter Prospective Open Label Clinical Safety Evaluation of Re-Injection of NX-1207 for the Treatment of BPH: 1-7 Years Apart.”
 136. **Endo Pharmaceutical** 7/2011: EN3329-301 “A Phase 3B, Randomized, Open-Label, Multi-Center Study to Evaluate the Efficacy and Safety of Maintenance Therapy with Valrubicin Versus No Maintenance, in Subjects Treated with Valrubicin Induction for Carcinoma in Situ (CIS) of the Bladder.”
 135. **Dendreon Corporation** 7/2011: P10-2 “A Randomized, Open-Label, Phase 2 Trial Examining the Sequencing of Sipuleucel-T and Androgen Deprivation Therapy in Men with Non-Metastatic Prostate Cancer and a Rising Serum Prostate Specific Antigen after Primary Therapy.”
 134. **University of California at San Francisco** 6/2011: 95982 “Cancer of the Prostate Strategic Urologic Research Endeavor.”
 133. **Spectrum Pharmaceutical** 5/2011: SPI-153-10-1 “An International, Multi-Center, Open Label, Randomized Study Assessing the Safety and Efficacy of a Monthly Dosing Regimen of Ozarelix versus Goserelin Depot (Zoladex®) in Men with Prostate Cancer.”
 132. **SWOG** 5/2011: S0337 “A Phase III Blinded Study of Immediate Post-TURBT Instillation of Gemcitabine versus Saline in Patients with Newly Diagnosed or Occasionally Recurring Grade I/II Superficial Bladder Cancer.”
 131. **UCSF** 03/2011: **CEASAR** “Comparative Effectiveness Analysis of Surgery and Radiation for prostate cancer.”
 130. **UCSF** 03/2011: **CaPSURE** “Cancer of the Prostate Strategic Urologic Research Endeavor.”
 129. **Janssen/Centecor Ortho Biotech** 2/2011: (Abitaterone PCR2005) “A Multicenter, Open-label, Single-arm, Phase 2 Study of Abiraterone Acetate plus Prednisone in Subjects with Advanced Prostate Cancer Without Radiographic Evidence of Metastatic Disease.”
 128. **Takeda Global Research and Development** 1/2011: “A Multi-Center Randomized, Double-Blind, Placebo and Allopurinol Controlled, Phase II Study to Evaluate Febuxostat in Medical Management of Subjects with Hyperuricosuria and Calcium Oxalate Stones.”
 127. **RTOG** 1/2011: 815 “A Phase III Prospective Randomized Trial of Dose-Escalated Radiotherapy With Or Without Short-Term Androgen Deprivation Therapy For Patients With Intermediate-Risk Prostate Cancer.”
 126. **RTOG** 1/2011: 534 “A Phase III Trial of Short Term Androgen Deprivation With Pelvic Lymph Node or Prostate Bed Only Radiotherapy (SPPORT) In Prostate Cancer Patients with a Rising PSA After Radical Prostatectomy.”
 125. **Pfizer** 1/2011: A0221094 “A 14 Week Randomized Parallel Group Placebo-Controlled Double-Blind Multicentre Study of Fesoterodine 8 mg in Overactive Bladder Patients with Sub-Optimal Response to Tolterodine 4 mg ER.”
 124. **Ferring** 1/2011: FE 200486 CS35A “An Open-Label, Multi-Center, Extension Trial, Evaluating the Long-Term, Progression-Free Survival, of Degarelix or Goserelin Three Month Dosing Regimens in Patients with Prostate Cancer, Requiring Androgen Deprivation Therapy.”
 123. **Astellas** 1/2011: “A Randomized, Double-Blind, Phase II, Efficacy and Safety Study of MDV3100 (ASP9785) vs. Bicalutamide in Castrate Men with Metastatic Prostate Cancer.”
 122. **Warner Chilcott** 2010: PR 01409 “An Open-Label Phase 3 Study to Evaluate the Long-Term Safety and Efficacy of WC3043 Tablets in Male Subjects with Erectile Dysfunction.”
 121. **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.”
 120. **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.”
 119. **Predictive Bioscience** 2010: PR-002 “Hematuria Evaluation Trial Device Trial.”
 118. **Predictive Bioscience** 2010: PR-001 “Hematuria Evaluation Trial Device Trial.”
 117. **Source Precision Medicine d.b.a Source MDx PRECISE** 2010: “A Prospective, Multi-Center PRostate Cancer Individual Signature Evaluation Trial (PRECISE) in Patients Undergoing Scheduled Prostate Biopsy.”
 116. **Pfizer** 11/2010: “A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Trial To Evaluate The Efficacy and Safety of Fesoterodine Flexible Dose Regimen In Vulnerable Elderly Patients With

- Overactive Bladder.”
115. **Auxilium** 10/2010: AUX-CC-804 “A Phase III, Double-Blind, Randomized, Placebo Controlled, Study of the Safety and Effectiveness of AA4500 Administered Twice Per Treatment Cycle, for Up to Four Treatment Cycles, in Men with Peyronie’s Disease.”
 114. **RTOG** 9/2010: 0621 “Adjuvant 3DCRT/IMRT in Combination with Androgen Suppression and Docetaxel for High Risk Prostate Cancer Patients Post-Prostatectomy.”
 113. **Astra Zeneca** 9/2010: “A Phase III, Randomized, Double-Blind Study, to Assess the Efficacy and Safety of Once Daily Administered SD 4054 10 mg in Non-Metastatic, Hormone- Resistant Prostate Cancer Patients.”
 112. **Ausio Pharmaceuticals** 8/2010: “A Randomized Double-Blind, Multi-Center, Placebo Controlled, Proof of Concept Trial to Assess the Efficacy and Safety of 4-Weeks Treatment with (AUS 131) in Subjects with BPH.”
 111. **Omeros** 6/2010: “A Double-Blind, Placebo Controlled, Concentration Escalating, Pharmokinetic Study, Evaluating the Systemic Absorption, Safety and Efficacy of (OMS 201) in Subjects Undergoing Ureteroscopic Treatment of Ureteral or Renal Collecting System Located Stones.”
 110. **Serenity Pharmaceuticals** 5/2010: “A Phase 3 Randomized, Double Blind, Placebo Control, Multi-Center Study to Investigate the Efficacy and Safety of SER120 Nasal Spray Formulation in Patients with Nocturia.”
 109. **Urovalve** 5/2010: “Assessment of the Surinate® Bladder Management System for Urinary Retention in Men.”
 108. **Health Discovery Corporation** 5/2010: “A Preliminary Validation of a Four Gene Signature Urine Test for the Early Detection of Prostate Cancer.” 101. **Watson** 12/2009: 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.”
 107. **Nymox** 3/2010: NX02-0017 “Phase III Multi-Center, Prospective, Randomized, Parallel-Group, Placebo Controlled, Double-Blind, Clinical Evaluation of NX-12-07 for the Treatment of BPH.”
 106. **Health Discovery Corporation** 3/2010: “Validation of a Four Gene Signature Urine Test for the Early Detection of Prostate Cancer (Study 2).”
 105. **Amgen** 2/2010: 20080560 “A Double-Blind, Placebo-Controlled Study to Evaluate New or Worsening Lens Opacifications in Subjects with Non-Metastatic Prostate Cancer Receiving Denosumab for Bone Loss Due to Androgen-Deprivation Therapy.”
 104. **Merck** 2009: V935-002 “A Phase I Investigation of the Safety, Tolerability and Immunogenicity of V934/V935 hTERT Vaccination in Cancer Patients with Selected Solid Tumors.” 102. **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.”
 103. **Merck** 2009: V934-001 “A Phase I Investigation of the Safety, Tolerability and Immunogenicity of V934/V935 hTERT Vaccination in Cancer Patients with Selected Solid Tumors.”
 102. **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.”
 100. **Ferring** 9/2009: 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.”
 99. **Allergan** 9/2009: A Double Blind, Randomized, Placebo Controlled Study, of the Effects on Spermatogenesis with Botox Botulinum Toxin Type A, Purified Neurotoxin Complex to treat the signs and Symptoms of BPH.”
 98. **Spectrum Pharmaceutical** 6/2009 A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Trial of the Safety and Efficacy of Ozarelix, in Patients with Lower Urinary Tract Symptoms (LUTS) due to Benign Prostatic Hypertrophy (BPH).”
 97. **Watson** 4/2009: 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.”
96. **Ferring** 4/ 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.”
 95. **Ferring** 3/2009: FE 200486 CS37 “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.”
 94. **Glaxo Smith Kline** 2/2009: ARI103094 “Follow-Up Study for REDUCE Study Subjects.”
 93. **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.”
 92. **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.”
 91. **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.”
 90. **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.”
 89. **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.”
 88. **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.”
 87. **Astellas** 11/2007: VESICARE 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.”
 86. **Pfizer** 10/2007: “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.”
 85. **Glaxo Smith Kline** 10/2007: AVO108943 “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.”
 84. **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.”
 83. **TheraVida Inc.** 9/2007: THVD-101 “A Combination of an Antimuscarinic and Muscarinic Agonist vs. an Antimuscarinic Agent, Alone in Subjects with OAB.”
 82. **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.”
 81. **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 Undecanoate in Hypogonadal Men.”

80. **Astellas** 5/2007: 178-CL-060 “A Phase 2, Randomized, Double-Blind, Parallel Group, Placebo Controlled, Multi-Center Study to Evaluate the Urodynamics and Safety of YM178 in Male Subjects with Lower Urinary Tract Symptoms (LUTS) and Bladder Outlet Obstruction (BOO).”
79. **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.”
78. **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.”
77. **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.”
76. **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.”
75. **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 (UI), Urgency, Frequency) In Overactive Bladder Subjects Who Were Dissatisfied with Their Most Recent Antimuscarinic OAB Medication Thera
74. **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.”
73. **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.”
72. **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.”
71. **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.”
70. **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.”
69. **GTX Pharmaceuticals** 04/2006: G400204 “A Randomized, Double-Blind, Placebo-Controlled, Multicenter Efficacy and Safety Extension Study of Toremifene Citrate for the Prevention of Bone Fractures in Men with Prostate Cancer on Androgen Deprivation Therapy.”
68. **Pharmacia** 2/2006: NQ4-99-02-006 “A Phase IIb/III Chemo Prevention Trial of Celecoxib to Prevent Recurrence of Superficial Bladder Cancer.”
67. **GTX Pharmaceuticals** 11/2005: G300204 “A Randomized, Double-Blind, Placebo-Controlled, Multicenter Efficacy and Safety Extension Study of Toremifene Citrate for the Prevention of Bone Fractures in Men with Prostate Cancer on Androgen Deprivation Therapy.”
66. **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 (UI), Urgency, Frequency) In Overactive Bladder Subjects, Who Were Dissatisfied With Their Most Recent Antimuscarinic OAB Medication Therapy.”
65. **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.”

64. **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.”
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62. **Ortho-McNeil** 9/2005: CAPSS-349 “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).”
61. **Medici Nova** 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.”
60. **Hoffman La Roche** 7/2005: NU18191 “Evaluation of Patients Who Completed More Than 180 Days of Active Treatment with Ro 115-1240.”
59. **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.”
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56. **Eli Lilly & Co.** 5/2005: FIJ-US-SBCD “Evaluation of Efficacy and Safety of Duloxetine HCl in Women of Different Demographic Characteristics and Comorbidities with Stress UI.”
55. **Glaxo Smith Kline** 04/2005: B3P102087 “A Twelve-Week Randomized, Double Blind, Placebo-Controlled, Parallel Group Proof of Concept Dose Ranging Study to Assess the Efficacy, Safety and Tolerability as well as the Pharmacokinetic Profile of 100 mg once daily and 25 mg and 50 mg Twice Daily of Oral Solabegron (GW427353) vs. Placebo and Extended Release Tolterodine Tartrate, as an Active Treatment Arm, in women with Overactive Bladder.”
54. **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.”
53. **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.”
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