LUGPA 2023 REGIONAL MEETING

Leveraging Technology: Enhancing Practice Performance

May 5-6, 2023

JW Marriott Scottsdale Camelback Inn Resort & Spa
Scottsdale, AZ

LUGPA
Integrated Practices
Comprehensive Care

LUGPA 2023 Regional Meeting:
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THANK YOU!

WELCOME RECEPTION SPONSOR

FRIDAY, MAY 5

6:00PM – 7:00PM

ARIZONA BALLROOM

(Salons I, J, K, L)

JW Marriott Scottsdale Camelback Inn Resort & Spa

SCOTTSDALE, AZ

CardinalHealth™

Join Us!

Reception at El Chorro (South Lawn)

Saturday, May 6

4:30pm – 6:30pm

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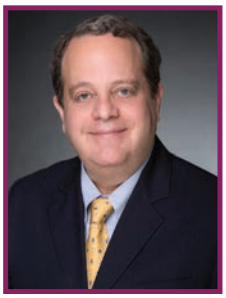
LUGPA 2023 Regional Meeting:
WELCOME



Dear Colleagues:

On behalf of the LUGPA Board of Directors, welcome to the 2023 Regional Meeting. We are so delighted to be meeting in Scottsdale, AZ.

This year's theme, ***Leveraging Technology: Enhancing Practice Performance*** reflects how LUGPA groups can use technology to improve efficiency, communication, access to care, and clinical advancement. This interactive program will allow you to learn about strategies to grow your practice and overcome barriers to implementing technology to improve patient care.

Kicking off the meeting, participants will have the opportunity to openly exchange ideas and develop a plan to promote patient access to care and ways to capture market share to increase practice revenue by using technology. During this interactive session each plan will be evaluated, and participants of the best plan will be awarded a gift card. We will also hear from a panel of LUGPA practices about how they leveraged technology to increase operational efficiencies and improved quality of patient care in their practice. Other highlights of the meeting include a round-table discussion with industry partners on meaningful ways to implement new solutions in their practice. For our last session, we have organized a panel of physician leaders and advanced practice providers to discuss best practices of integrating advanced practice providers into your urology practice. Lastly, we look forward to seeing you at the reception on Saturday at El Chorro.

We would like to thank our Industry Supporters, for without their support, this meeting would not be possible.

Thank you for attending the 2023 Regional Meeting, for your membership and for your continued support. Please join us as we acknowledge our achievements as the only nonprofit trade association dedicated to the advancement and preservation of the independent practice of urology, as we begin our 15th year.

Sincerely,

Evan R. Goldfischer, MD
President, LUGPA

Jeffrey Spier, MD
Chair, LUGPA Program Committee

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LUGPA 2023 Regional Meeting:
OVERVIEW

Friday, May 5, 2023

TIME	SESSION TITLE	LOCATION
5:00pm-7:00pm	Meeting Registration / Information	Arizona Registration Desk South
6:00pm-7:00pm	Exhibit Hall	Arizona Ballroom (SALONS I, J, K, L)
6:00pm-7:00pm	Welcome Reception	Arizona Ballroom (SALONS I, J, K, L)

Saturday, May 6, 2023

TIME	SESSION TITLE	LOCATION
7:00am-4:00pm	Meeting Registration/Information	Arizona Registration Desk South
7:30am-8:30am	Industry Sponsored Breakfast	Arizona Ballroom (Salon G)
10:00am-10:30am	Break in the Exhibit Hall	Arizona Ballroom (SALONS I, J, K, L)
12:00pm-1:00pm	Industry Sponsored Lunch	Arizona Ballroom (Salon G)
2:45pm-3:00pm	Break in the Exhibit Hall	Arizona Ballroom (SALONS I, J, K, L)
4:30pm-6:30pm	Social Activity – Reception at El Chorro (south lawn)	5550 E Lincoln Dr, PARADISE VALLEY, AZ

LUGPA 2023 Regional Meeting:

PROGRAM AGENDA

Saturday, May 6, 2023

TIME	SESSION TITLE	LOCATION
7:00am-4:00pm	**Meeting Registration / Information**	**Arizona Registration Desk South**
7:30am-8:30am	**Industry Sponsored Breakfast**	**Arizona Ballroom (Salon G)**
8:30am-8:35am	**President's Welcome** Evan Goldfischer, MD	**Arizona Ballroom (Salon G)**
8:35am-8:45am	**Welcome and Introductions** Jeffrey Spier, MD	**Arizona Ballroom (Salon G)**
8:45am-9:30am	**Icebreaker Sessions: Topics**	**Arizona Ballroom (Salon G)**
9:30am-10:00am	**Industry Roundtable Showcase – Group 1**	**Arizona Ballroom (Salon G)**
10:00am-10:30am	**Break in the Exhibit Hall**	**Arizona Ballroom (SALONS I, J, K, L)**
10:30am-11:30am	**Group presentations and selection of best plan by Judges**	**Arizona Ballroom (Salon G)**
11:30am-12:00pm	**Industry Roundtable Showcase – Group 2**	**Arizona Ballroom (Salon G)**
12:00pm-1:00pm	**Industry Sponsored Lunch**	**Arizona Ballroom (Salon G)**
1:00pm-1:30pm	**Industry Roundtable Showcase – Group 3**	**Arizona Ballroom (Salon G)**
1:30pm-2:15pm	**Leveraging Technology to Create Efficiencies and Drive Quality in the Patient Care Journey** Moderator: David Albala, MD; Panelists: Dave Carpenter, Ben Coons, MD, Twila Puritty	**Arizona Ballroom (Salon G)**
2:15pm-2:45pm	**Industry Roundtable Showcase – Group 4**	**Arizona Ballroom (Salon G)**
2:45pm-3:00pm	**Break in the Exhibit Hall**	**Arizona Ballroom (Salons I, J, K, L)**
3:00pm-4:00pm	**Best Practices to Integrate APPs into Your Practice** Moderators: Josh Langston, MD; Neal Patel, MD Panelists: Paloma Becker, NP;Heather Bridgeford, MSN, RN, FNP-C; Chelsie Ferrell, PA; Matt Gilbert, NP-C; Joy Maulik, CRNP; Sarah Nayebosadri, PA-C	**Arizona Ballroom (Salon G)**
4:00pm-4:15pm	**Wrap-up and Closing Comments** Jeffrey Spier, MD	**Arizona Ballroom (Salon G)**
4:30pm-6:30pm	**Social Activity – Reception at El Chorro – South Lawn**	**5550 E Lincoln Dr, Paradise Valley, AZ**

LUGPA 2023 Regional Meeting:

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LUGPA 2023 Regional Meeting:
FACULTY BIOGRAPHIES

Jeffrey Spier, MD, Chair, LUGPA Program Committee

Dr. Spier is President of Rio Grande Urology (RGU) founded in 2008 serving West Texas and Southern New Mexico. RGU has 23 providers with 5 offices and 2 radiation centers employing over 250 staff in El Paso, Texas and Las Cruces, New Mexico. Dr. Spier has overseen the tremendous growth of RGU, becoming the largest private practice physician group in the region. Rio Grande Urology continues to expand with the formation of the Rio Grande Cancer Specialists (RGCS) providing radiation therapy as well as the RGCS Advanced Prostate Cancer. This center of excellence includes clinical research with ongoing expansion into other genitourinary oncologic conditions. "RGU is committed to serving the urologic and oncologic needs of their patients, providing state of the art and compassionate care," said Dr. Spier.

Dr. Spier is board certified by the American Board of Urology and member of the American Urological Association and South Central Section of the AUA. He graduated from the University of Texas Medical Branch in Galveston, Texas where he also completed his Urology residency training. He currently serves on the Large Urology Group Practice Association (LUGPA) Board of Directors and serves as secretary. He is currently President of the El Paso County Medical Society, board member of the University of Texas at Galveston Alumni Board of Trustees and has served on the board of the Texas Urological Society.

David M. Albala, MD

Dr. David M. Albala graduated with a geology degree from Lafayette College in Easton, Pennsylvania. He completed his medical school training at Michigan State University and went on to complete his surgical residency at the Dartmouth- Hitchcock Medical Center. Following this, Dr. Albala was an endourology fellow at Washington University Medical Center under the direction of Ralph V. Clayman. He practiced at Loyola University Medical Center in Chicago and rose from the ranks of Instructor to full Professor in Urology and Radiology in eight years. Ten years later, he became a tenured Professor at Duke University Medical Center in North Carolina. At Duke, he was Co-Director of the Endourology fellowship and Director for the Center of Minimally Invasive and Robotic Urological Surgery. He has over 217 publications in peer-reviewed journals and has authored three textbooks in endourology and five in general urology. He is the Editor-in-Chief of the Journal of Robotic Surgery. He serves on the editorial board for Medical Reviews in Urology, Current Opinions in Urology and Urology Index and Reviews. He serves as a reviewer for eight surgical journals. He currently sits on the Board of Directors for the Large Urology Group Practice Association (LUGPA) as well as US Urology Partners (USUP). He is a Visiting Professor in the Department of Urology at SUNY Downstate Health Sciences University. In addition, he was ranked among the top 2% of urologists in the world by a Stanford University study done in May, 2021.

At the present time he is Chief of Urology at Crouse Hospital and a member of Associated Medical Professionals in Syracuse, New York. He is considered a national and international authority in laparoscopic and robotic urological surgery and has been an active teacher in this area for over 20 years. His research and clinical interests have focused on robotic urological surgery. In addition, other clinical interests include minimally invasive treatment of benign prostatic hypertrophy (BPH), biomarkers in prostate cancer, and the use of fibrin sealants in surgery. He has been a Visiting Professor at numerous institutions across the United States as well as overseas in countries such as India, China, Iceland, Germany, France, Japan, Brazil, Australia, and Singapore. In addition, he has done operative demonstrations in over 32 countries and 23 states. He has trained 19 fellows in endourology and advanced robotic surgery. In addition, Dr. Albala is a past White House Fellow who acted as a special assistant to Federico Pena, Secretary of Transportation, on classified and unclassified public health related issues.

Paloma Becker, ACNP

Ms. Paloma Becker is an acute care nurse practitioner. She received her Master's degree from the University of Texas at El Paso. She has worked with Rio Grande Urology in El Paso Texas for the past 6 years and is a member of the American Urological Association. Ms. Becker serves the inpatient and outpatient urology populations. She treats a wide variety of general urologic conditions some of which include, but are not limited to: kidney stones, bladder cancer, prostate cancer, overactive bladder, as well as caring for acutely ill patients in the hospital during call coverage.

Heather N. Bridgeford, RN, MSN, FNP-C

Ms. Bridgeford has provided urology care at Urology San Antonio for nine years with a focus in women's urology including treatment for overactive bladder, urinary incontinence, urinary tract infections, pelvic floor prolapse using urodynamics. She completed her bachelor's and graduate degrees in nursing at the University of Texas Health Science Center at San Antonio. Ms. Brideford is certified as a family nurse practitioner.

David M. Carpenter

As the Chief Executive Officer of Minnesota Urology, the largest independent urology medical group in the upper mid-west, Dave is privileged to offer his experience as a medical group administrator and business leader. Prior to arriving at Minnesota Urology, Dave spent 9 years as Chief Executive Officer of Physicians Neck and Back Clinics (PNBC), a Minnesota-based medical practice specializing in the non-operative treatment of chronic spinal disorders. Prior to PNBC, Dave was a company co-founder and Vice President of Prevention First, Inc., a healthcare solutions company offering programs to reduce workers' compensation costs associated with back and upper extremity injuries.

Before arriving in Minnesota, Dave served eight years as a faculty member within the University of Florida College of Medicine. During his tenure at UF, Dave worked closely with the late Dr. Michael Pollock, Ph.D., and Arthur Jones, founder of Nautilus and MedX exercise/rehabilitation equipment, to develop international programs for the prevention and rehabilitation of chronic spinal disease. He has lectured and taught throughout the world in the area of resistance training and active spinal exercise rehabilitation and has authored and co-authored more than 50 scientific articles. Dave holds a master's degree in Exercise Science from the University of Florida and is a certified facilitator of The 7 Habits of Highly Effective People. He and his wife Jenifer have a twin daughter (Chloe), and son (Hudson). Dave enjoys golf, woodworking, leathercraft, relaxing in his hand-built tree house overlooking the St. Croix River, and caddying for his son.

Benjamin Coons, MD

Dr. Coons is board-certified by the American Board of Urology and is a member of the American Urological Association, Colorado Medical Society, El Paso County Medical Society, and Rocky Mountain Urological Society. He is on the board of the Rocky Mountain Kidney Stone Center and serves on the program committee for the Large Urology Group Practice Association.

Dr. Coons earned his Bachelor of Science from the University of Notre Dame and his Master of Medical Science from Hahnemann University in Philadelphia, Pennsylvania. He completed his Doctor of Medicine at Indiana University School of Medicine in Indianapolis, Indiana, where he received induction into Alpha Omega Alpha Honor Medical Society.

Dr. Coons completed an internship at Vanderbilt University in Nashville, Tennessee, and finished his training with a residency in urology at Vanderbilt University, where he trained in extensive laparoscopic, robotic, and reconstructive procedures. Dr. Coons completed the first single incision laparoscopic nephrectomy in Southern Colorado. He's published research on kidney cancer and sacral neuromodulation, an advanced treatment for refractory urinary urgency/frequency. He has two decades of experience and specializes in complex oncology, da Vinci® robotic surgery, laparoscopy, and male reconstructive procedures.

Outside of the office, Dr. Coons enjoys spending time with his wife and two children, skiing, hiking, and watching Notre Dame football. He looks forward to providing exceptional care to patients at The Urology Center of Colorado.

Chelsie Ferrell, PA

Mrs. Ferrell received her Bachelor of Science Degree in Biology from the University of Missouri in 2009. She received her Masters of Science degree in Medical Science from Nova Southeastern University in 2013, where she was a Chancellors List Scholar

She works in general urology but also has a special emphasis on advanced prostate cancer. She is the chair of AUI's APP Committee and has experience as a national speaker/educator.

Matt Gilbert, NP

Matthew Gilbert has been with Urology of Virginia specializing in men's health and general urology since 2017. He is a member of the Androgen Society and the American Urological Association, and has advanced training in testosterone therapy, erectile dysfunction, male infertility, benign prostatic hyperplasia, and kidney stone disease. He also performs the majority of MRI guided prostate biopsies for Urology of Virginia with well over 1,000 biopsies performed.

Evan P. Goldfischer, MD, MBA, CPI

Dr. Goldfischer received his BA from Tufts University and his MD from Cornell University Medical College. He completed his internship in general surgery and his residency in urology at the University of Chicago. He completed a fellowship in endourology under the direction of Arthur Smith at Long Island Jewish Medical Center. Dr. Goldfischer received his MBA from the University of Massachusetts and is a Certified Physician Executive. He served as the co-founding CEO of Premier Medical Group of the Hudson Valley, as well as founding Director of Research.

Dr. Goldfischer has written over 100 peer-reviewed abstracts and publications and has lectured on six continents. In addition, he was elected to the LUGPA Board of Directors in 2014 currently serving as President. He is the Editor-in-Chief of Practice Management for Urology Groups: LUGPA's Guidebook Second Edition published in 2020 and is the author of Even Urologists Get Kidney Stones – A Guide to Prevention and Treatment, published in 2018.

Joshua Langston, MD

Dr. Joshua Langston is a urologist and the Chief Medical Officer at Urology of Virginia, a 50 provider group based in Virginia Beach, VA. After residency training at the University of North Carolina – Chapel Hill, he completed a fellowship in Andrology & Male Reconstructive Urology at the Institute of Urology in London, England. His clinical practice focuses on men's health and cancer survivorship, and he founded and directs Men's Health Virginia, a division of Urology of Virginia.

In addition to clinical pursuits, Dr. Langston has a strong interest in health policy, advocacy and physician leadership in medicine. He was selected as the American Urological Association's 2017 Holtgrewe Legislative Fellow, spending time as a health policy legislative advisor in the U.S. Senate. He is a member of the Political Affairs Committee for the Large Urology Group Practice Association where he was awarded their 2019 Advocate of the Year award. He is Co-Chair of the Regulatory Affairs Committee and a member of the Political Affairs and Practice Management Committees for the American Urological Association. While in the U.K., Dr. Langston was selected to participate in the Executive Mentoring Program sponsored by NHS England for doctors with special interest in executive leadership in medicine. He serves on the Board of Directors for the American Society for Men's Health, as well as a number of other boards and advisory groups.

LUGPA 2023 Regional Meeting:
FACULTY BIOGRAPHIES

Joy Maulik, CRNP

Joy Maulik began his career in healthcare in 2007 and graduated with his Nurse Practitioner degree from Wilmington University in 2015. There he was selected as class Valedictorian in addition, to being awarded a certificate in Academic Excellence. During his career he has assumed various roles in both clinical and leadership positions. His experience ranges from clinical nurse supervisor, community based primary care, and Director of Critical Care for a level III trauma center. He is currently practicing at Chesapeake Urology specializing in general Urology with sub specialization in Prostate Cancer and Men's health. He also serves as member of lead APP team with United Urology, as well as Co-Chair of APP council at Tidal Health Care. He lives on the Eastern Shore of Maryland, with his wife of sixteen years and his eleven year old twins. He believes in learning from defects and investing in processes which cultivates optimal outcome and relationship building.

Sarah Nayebosadri, PA-C

Sarah Nayebosadri is a Physician Assistant with Advanced Urology in the Atlanta area. She pursued a Bachelors degree in Biomedical Engineering at Georgia Institute of Technology where she graduated summa cum laude. She attended Mercer University pursuing a Master of Medical Science in Physician Assistant Studies. She received the Scholastic Achievement Award for having the highest GPA of her physician assistant class. Sarah has worked at Advanced Urology for five years. She has particular interest in overactive bladder, benign prostatic hyperplasia, interstitial cystitis, as well as numerous other general urology ailments. She also assists in a variety of open and robotic surgical cases with many of the physicians in her practice. She performs clinic procedures and assists with outpatient ambulatory surgery center procedures as well.

Neal Patel, MD

Chief Technology Officer and Director of Robotic Surgery at Advanced Urology Institute of Georgia, PC in Snellville, GA. Dr. Neal Patel , a Georgia native, earned his medical degree from Chicago Medical School as part of an engineering in medicine program with the Illinois Institute of Technology where he graduated Cum Laude with a degree in Molecular Biochemistry and Biophysics. After completing residency in Urologic Surgery at Rutgers Robert Wood Johnson Medical School in New Jersey, he joined the USC Institute of Urology as a Felix and Mildred Yip Fellow in Advanced Robotics and Laparoscopy.

Dr. Patel has been active with the American Medical Association, the Illinois State Medical Society and the Chicago Medical Society. He has served on the Board of Trustees of the Chicago Medical Society, and has held multiple leadership positions within organized medicine at both local and national levels. In 2009, Dr. Patel was invited to attend the TEDMED inaugural conference in San Diego and has since been an invited alumnus.

Twila Puritty

Twila Puritty is the CEO of Wichita Urology and has been with the practice for 9 years. Wichita Urology is a group of 15 providers with 3 locations in Wichita and 13 outreach locations in rural Kansas communities. Prior to joining Wichita urology, Twila had a 25+ year career managing radiology groups and imaging centers in Florida, California, Oklahoma, Nebraska and Kansas.

In her nine years with Wichita Urology, the practice has grown by building a free-standing radiation oncology facility, adding a successful clinical trial program, establishing an advanced prostate cancer clinic, developing catheter dispensing, and in-office dispensing programs. The group recently opened a new 26,000 sq. ft. facility. The building houses a 14,000 sq. ft. ambulatory surgery center that opened the summer of 2021. Mrs. Puritty and the Wichita Urology physicians have also developed multiple LLCs for equipment and building leasing.

Twila's professional passions are facilitating growth initiatives, increasing clinical productivity, and enhancing collection efforts through microanalysis with the result of maximizing shareholder wealth. Twila and her husband Ross have five children.

Scott Sellinger, MD

Dr. Sellinger has been a partner at Southeastern Urological Center, now a division of Advanced Urology Institute, since 1991. He received his BS degree in Chemistry from Syracuse University, and attended Medical School at the University of Florida in Gainesville. He completed his Urology residency at the University of Florida and has lived in Tallahassee for over 30 years. He was President of the Capital Medical Society in 2003, and served as President of the Florida Urological Society in 2005. In 2018, he served as President of the Southeastern Section of the American Urological Association (SESAUA). In 2019, he served as President of the American Association of Clinical Urologists (AACU). In addition to his urology specific work, Dr. Sellinger has developed a special interest in risk management and prevention of medical errors and has lectured extensively on this subject matter. He is also interested in large group practice development and management. For several years, Dr. Sellinger has served on the board of Advanced Urology Institute (AUI) representing his care center in Tallahassee. In January 2021, he became the second President of AUI, now one of the largest independent urology practices in the United States. Dr. Sellinger currently chairs the Advanced Prostate Cancer (APC) Committee and oversees seven APC clinics within AUI. Since 2015, has also served on the Large Urology Group Practice Association (LUGPA) Board of Directors, where he currently serves as President-Elect. At LUGPA, he is proud to represent over 2300 Urologists by working to preserve and advance the independent practice of urology.

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LUGPA 2023 Urology Regional Meeting:

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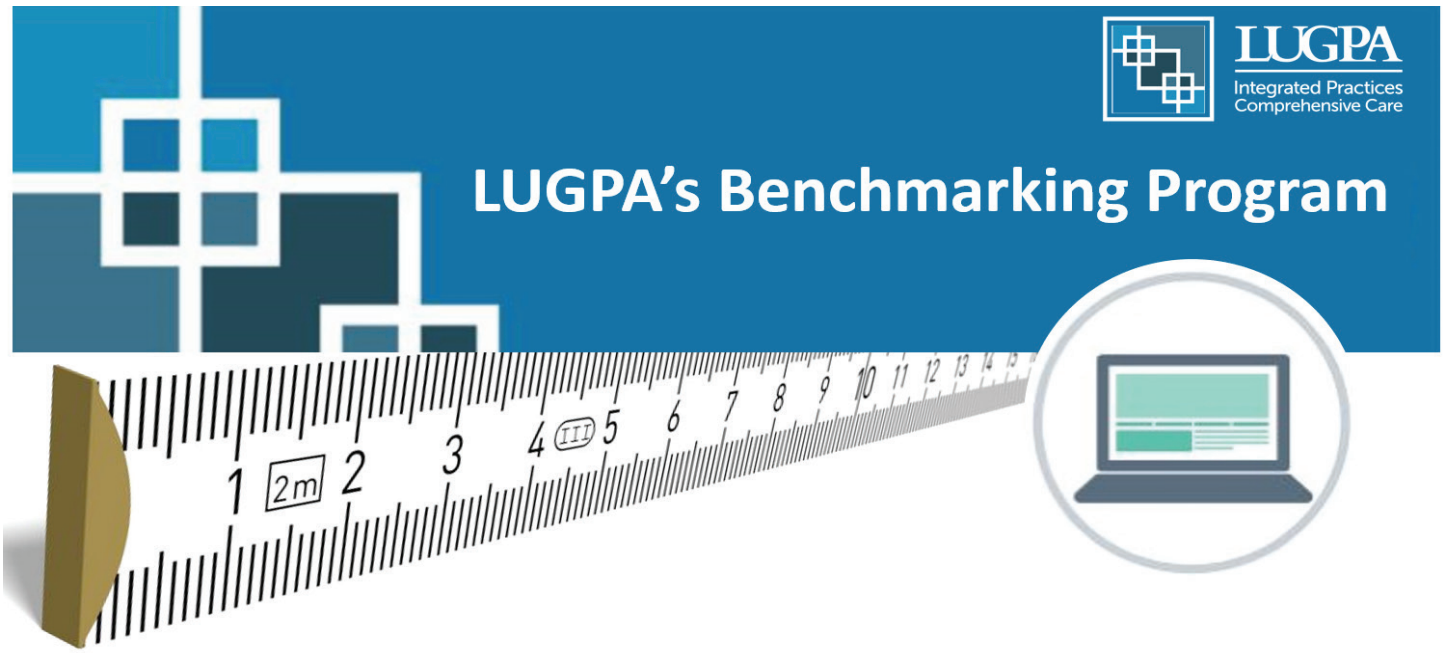

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These benchmarking metrics will also assist LUGPA in providing educational and research programs as well as provide analytical support to key LUGPA health policy initiatives.

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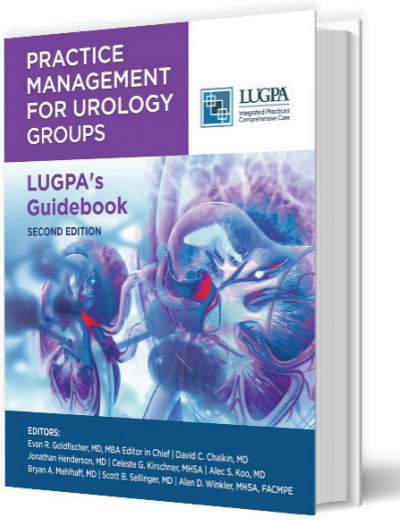
For more information on the benchmarking program and how to join, please contact Kathy Stack at kstack@lugpa.org or (312) 728-0137. If you are not a current InfoDive user and would like more information or a product demonstration, please contact info@intrinsiq.com.



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Are you an early-career urologist practicing less than 15 years?

LUGPA FORWARD

If yes, please let us know so we can add you to the LUGPA Forward group communication list!

What is LUGPA Forward?
LUGPA Forward is the "go to" group for early-career physicians within LUGPA member practices providing education and networking opportunities. It also provides a voice for you and your peers to be heard by the LUGPA Board of Directors.

If you are an early-career physician practicing less than 15 years,
please provide the following to **Sommer Thornton, sthornton@lugpa.org:**

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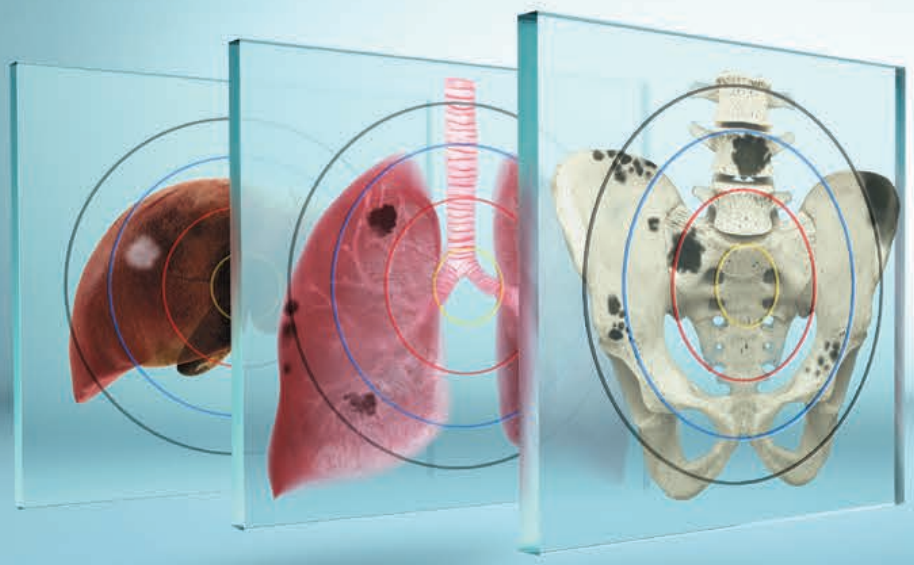

Not an actual patient.

Indication

PLUVICTO™ (lutetium Lu 177 vipivotide tetraxetan) is indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy.

IMPORTANT SAFETY INFORMATION

Risk From Radiation Exposure

PLUVICTO contributes to a patient's long-term cumulative radiation exposure, which is associated with an increased risk for cancer.

Minimize radiation exposure to patients, medical personnel, and household contacts during and after treatment with PLUVICTO consistent with institutional practices, patient treatment procedures, Nuclear Regulatory Commission patient-release guidance, and instructions to the patient for follow-up radiation protection.

Ensure patients increase oral fluid intake and advise them to void as often as possible to reduce bladder radiation.

To minimize radiation exposure to others, advise patients to limit close contact (less than 3 feet) with household contacts for 2 days or with children and pregnant women for 7 days, to refrain from sexual activity for 7 days, and to sleep in a separate bedroom from household contacts for 3 days, from children for 7 days, or from pregnant women for 15 days.

Myelosuppression

PLUVICTO can cause severe and life-threatening myelosuppression. In the VISION study, grade 3 or 4 decreased hemoglobin (15%), decreased platelets (9%), decreased leukocytes (7%), and decreased neutrophils (4.5%) occurred in patients treated with PLUVICTO. Grade ≥3 pancytopenia occurred in 1.1% of patients (including 2 fatal events). Two deaths (0.4%) due to intracranial hemorrhage and subdural hematoma in association with thrombocytopenia were observed. One death due to sepsis and concurrent neutropenia was observed.

Perform complete blood counts before and during treatment with PLUVICTO. Withhold, reduce dose, or permanently discontinue PLUVICTO and clinically treat patients based on severity of myelosuppression.

Renal Toxicity

PLUVICTO can cause severe renal toxicity. In the VISION study, grade 3 or 4 acute kidney injury (3%) and increased creatinine (0.9%) occurred in patients treated with PLUVICTO.

Advise patients to remain well hydrated and to urinate frequently before and after administration of PLUVICTO. Perform kidney function laboratory tests, including serum creatinine and calculated creatinine clearance (CrCl), before

In the pivotal phase 3 VISION trial, PLUVICTO + BSOC vs BSOC alone[1-4]:

Alternate Primary End Points

Significantly improved median OS[1,2]

15.3 vs **11.3**
months, respectively

HR=0.62
(95% CI, 0.52-0.74)
P<0.001

(N=551 vs 280)

Significantly improved rPFS[3]

8.7 vs **3.4**
months, respectively

HR=0.40
(95% CI, 0.31-0.52)
P<0.001

(N=385 vs 196)

Key Secondary End Point

Significantly improved ORR[1,4,a]

30% vs **2%**
of patients, respectively

CR: 6% vs 0%
PR: 24% vs 2%
P<0.001[b]

(N=319 vs 120)[c]
(ORR=CR+PR)

Interpretation of the magnitude of the rPFS effect was limited due to a high degree of censoring from early dropout in the control arm

[a] ORR is reported as a measure of response in soft tissue disease, lymph node, or visceral lesions. [b] Stratified Wald's Chi-square test 2-sided *P* value. [c] Patients with evaluable disease at baseline.

VISION trial design[1,2]

VISION was an international, prospective, open-label, multicenter, randomized phase 3 clinical trial evaluating PLUVICTO in 831 adult patients with PSMA-positive mCRPC previously treated with at least 1 AR pathway inhibitor and 1 or 2 taxane regimens. Participants were randomized in a 2:1 ratio to receive PLUVICTO (7.4 GBq every 6 weeks for up to 6 cycles) + protocol-permitted BSOC or BSOC alone.

and during treatment. Withhold, reduce dose, or permanently discontinue PLUVICTO based on severity of renal toxicity.

Embryo-Fetal Toxicity

The safety and efficacy of PLUVICTO have not been established in females. Based on its mechanism of action, PLUVICTO can cause fetal harm. No animal studies using lutetium Lu 177 vipivotide tetraxetan have been conducted to evaluate its effect on female reproduction and embryo-fetal development; however, all radiopharmaceuticals, including PLUVICTO, have the potential to cause fetal harm. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with PLUVICTO and for 14 weeks after the last dose.

Infertility

The recommended cumulative dose of 44.4 GBq of PLUVICTO results in a radiation-absorbed dose to the testes within the range where PLUVICTO may cause temporary or permanent infertility.

Adverse Reactions

The most common adverse reactions (≥20%) occurring at a higher incidence in patients who received PLUVICTO plus best standard of care (BSoC) were fatigue, dry mouth, nausea, anemia, decreased appetite, and constipation. Clinically relevant adverse reactions in <5% of patients included dry eye, vertigo, and pancytopenia (including bicytopenia).

Laboratory Abnormalities

The most common laboratory abnormalities that worsened from baseline in ≥30% of patients who received PLUVICTO plus BSoC were decreased lymphocytes, decreased hemoglobin, decreased leukocytes, decreased platelets, decreased calcium, and decreased sodium.

Please see Brief Summary of full Prescribing Information on the following pages.

AR, androgen receptor; ARPI, androgen receptor pathway inhibitors; BSOC, best standard of care; CR, complete response; mCRPC, metastatic castration-resistant prostate cancer; ORR, overall response rate; OS, overall survival; PR, partial response; PSMA, prostate-specific membrane antigen; PSMA+, PSMA positive; rPFS, radiographic progression-free survival.

Learn more at PluvictoHCP.com

References:

1. Pluvicto [prescribing information]. Millburn, NJ: Advanced Accelerator Applications USA, Inc. **2.** Sartor O et al; VISION Investigators. *N Engl J Med*. 2021;385(12): 1091-1103. doi: 10.1056/NEJMoa2107322. **3.** Data on file. VISION [PSMA-617-01] study. Novartis Pharmaceuticals Corp; 2021. **4.** Sartor O et al; VISION Investigators. *N Engl J Med*. 2021;385(12)(suppl): 1091-1103. doi: 10.1056/NEJMoa2107322.

Advanced Accelerator Applications
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224350 7/22

PLUVICTO™ (lutetium Lu 177 vipivotide tetraxetan) injection, for intravenous use
Initial U.S. Approval: 2022

BRIEF SUMMARY: Please see package insert for full prescribing information.

1 INDICATIONS AND USAGE

PLUVICTO is indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Risk From Radiation Exposure

PLUVICTO contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk for cancer.

Minimize radiation exposure to patients, medical personnel, and household contacts during and after treatment with PLUVICTO consistent with institutional good radiation safety practices, patient treatment procedures, Nuclear Regulatory Commission patient-release guidance, and instructions to the patient for follow-up radiation protection at home.

Ensure patients increase oral fluid intake and advise patients to void as often as possible to reduce bladder radiation.

Before the patient is released, the healthcare provider should explain the necessary radioprotection precautions that the patient should follow to minimize radiation exposure to others *[see Patient Counseling Information (17) in the full prescribing information]*. Following administration of PLUVICTO, advise patients to limit close contact (less than 3 feet) with household contacts for 2 days or with children and pregnant women for 7 days. Following administration of PLUVICTO, advise patients to refrain from sexual activity for 7 days. Following administration of PLUVICTO, advise patients to sleep in a separate bedroom from household contacts for 3 days, from children for 7 days, or from pregnant women for 15 days.

5.2 Myelosuppression

PLUVICTO can cause severe and life-threatening myelosuppression, including anemia, thrombocytopenia, leukopenia, and neutropenia. In the VISION study, Grade 3 or 4 decreased hemoglobin (15%), decreased platelets (9%), decreased leukocytes (7%), and decreased neutrophils (4.5%) occurred in patients treated with PLUVICTO. Grade ≥ 3 pancytopenia occurred in 1.1% (which includes two fatal events) in patients treated with PLUVICTO. Two deaths (0.4%) due to intracranial hemorrhage and subdural hematoma in association with thrombocytopenia were observed in patients who received PLUVICTO. One death due to sepsis and concurrent neutropenia was observed in patients who received PLUVICTO.

Perform complete blood counts before and during treatment with PLUVICTO. Withhold, reduce dose, or permanently discontinue PLUVICTO and clinically treat patients based on the severity of myelosuppression *[see Dosage and Administration (2.4) in the full prescribing information]*.

5.3 Renal Toxicity

PLUVICTO can cause severe renal toxicity. In the VISION study, Grade 3 or 4 acute kidney injury (3%) and increased creatinine (0.9%) occurred in patients treated with PLUVICTO.

Advise patients to remain well hydrated and to urinate frequently before and after administration of PLUVICTO. Perform kidney function laboratory tests, including serum creatinine and calculated CLcr, before and during treatment with PLUVICTO. Withhold, reduce dose, or permanently discontinue PLUVICTO based on the severity of renal toxicity *[see Dosage and Administration (2.4) in the full prescribing information]*.

5.4 Embryo-Fetal Toxicity

The safety and efficacy of PLUVICTO have not been established in females. Based on its mechanism of action, PLUVICTO can cause fetal harm *[see Clinical Pharmacology (12.1) in the full prescribing information]*. No animal studies using lutetium Lu 177 vipivotide tetraxetan have been conducted to evaluate its effect on female reproduction and embryo-fetal development; however, all radiopharmaceuticals, including PLUVICTO, have the potential to cause fetal harm. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with PLUVICTO and for 14 weeks after the last dose *[see Use in Specific Populations (8.1, 8.3)]*.

5.5 Infertility

PLUVICTO may cause infertility in males. The recommended cumulative dose of 44.4 GBq of PLUVICTO results in a radiation absorbed dose to the testes within the range where PLUVICTO may cause temporary or permanent infertility *[see Use in Specific Populations (8.3)]*.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Myelosuppression *[see Warnings and Precautions (5.2)]*
- Renal Toxicity *[see Warnings and Precautions (5.3)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of PLUVICTO was evaluated in the VISION study in patients with progressive, PSMA-positive mCRPC *[see Clinical Studies (14) in the full prescribing information]*. Of the 831 patients randomized, 734 patients received at least one dose of randomized treatment. Patients received at least one dose of either PLUVICTO 7.4 GBq (200 mCi) administered every 6 to 10 weeks plus BSoC (N = 529) or BSoC alone (N = 205). The median duration of exposure to randomized treatment was 7.8 months (range, 0.3 to 24.9) for patients who received PLUVICTO plus BSoC. Among patients who received PLUVICTO plus BSoC, the median number of doses of PLUVICTO received was 5 (range, 1 to 6). The median cumulative dose of PLUVICTO was 37.5 GBq (range, 7.0 to 48.3). The median duration of follow-up was 14.8 months for patients receiving PLUVICTO plus BSoC.

Serious adverse reactions occurred in 36% of patients who received PLUVICTO plus BSoC. Serious adverse reactions in > 1% of patients who received PLUVICTO plus BSoC included hemorrhage (4%), musculoskeletal pain (3.8%), sepsis (3.2%), anemia (2.8%), urinary tract infection (2.6%), acute kidney injury (1.7%), pneumonia (1.7%), pancytopenia (1.3%), pyrexia (1.3%), spinal cord compression (1.1%), and pulmonary embolism (1.1%).

Fatal adverse reactions occurred in 2.8% of patients who received PLUVICTO plus BSoC, including sepsis (0.9%), pancytopenia (0.6%), hepatic failure (0.4%), intracranial hemorrhage (0.2%), subdural hematoma (0.2%), ischemic stroke (0.2%), COVID-19 (0.2%), and aspiration pneumonia (0.2%).

PLUVICTO was permanently discontinued due to adverse reactions in 12% of patients. Adverse reactions leading to permanent discontinuation of PLUVICTO in ≥ 1% of patients who received PLUVICTO plus BSoC were anemia (2.8%), thrombocytopenia (2.8%), and leukopenia (including neutropenia) (1.7%).

Adverse reactions leading to a dose interruption of PLUVICTO occurred in 16% of patients. The most frequent (≥ 3%) adverse reactions leading to a dose interruption of PLUVICTO in patients who received PLUVICTO plus BSoC were anemia (5%) and thrombocytopenia (3.6%).

Adverse reactions leading to a dose reduction of PLUVICTO occurred in 6% of patients. The most frequent (≥ 1%) adverse reactions leading to a dose reduction of PLUVICTO in patients who received PLUVICTO plus BSoC were thrombocytopenia (1.9%) and anemia (1.3%).

The most common adverse reactions (≥ 20%) occurring at a higher incidence in patients who received PLUVICTO plus BSoC were fatigue, dry mouth, nausea, anemia, decreased appetite, and constipation.

The most common laboratory abnormalities that worsened from baseline in ≥ 30% of patients who received PLUVICTO plus BSoC were decreased lymphocytes, decreased hemoglobin, decreased leukocytes, decreased platelets, decreased calcium, and decreased sodium.

Table 3 and Table 4 summarize the incidence of adverse reactions and laboratory abnormalities, respectively.

Table 3: Adverse Reactions (≥ 5%) in Patients with PSMA-positive mCRPC Who Received PLUVICTO Plus BSoC in VISION

Adverse Reactions	PLUVICTO Plus BSoC (N = 529)		BSoC (N = 205)	
	All Grades (%)	Grades 3 to 4 (%)	All Grades (%)	Grades 3 to 4 (%)
General disorders				
Fatigue	43	6	23	1.5
Decreased appetite	21	1.9	15	0.5
Weight decreased	11	0.4	9	0
Peripheral edema[a]	10	0.4	7	0.5
Pyrexia	7	0.4	3.4	0
Gastrointestinal disorders				
Dry mouth[b]	39	0	0.5	0
Nausea	35	1.3	17	0.5
Constipation	20	1.1	11	0.5
Vomiting[c]	19	0.9	6	0.5
Diarrhea	19	0.8	2.9	0.5
Abdominal pain[d]	11	1.1	6	0.5

(continued)

Table 3: Adverse Reactions (≥ 5%) in Patients with PSMA-positive mCRPC Who Received PLUVICTO Plus BSoC in VISION

Adverse Reactions	PLUVICTO Plus BSoC (N = 529)		BSoC (N = 205)	
	All Grades (%)	Grades 3 to 4 (%)	All Grades (%)	Grades 3 to 4 (%)
Blood and lymphatic system disorders				
Anemia	32	13	13	4.9
Thrombocytopenia	17	8	4.4	1
Renal and urinary disorders				
Urinary tract infection[e]	12	3.8	1	0.5
Acute kidney injury[f]	9	3.2	6	2.9
Nervous system disorders				
Dizziness	8	0.9	4.4	0
Headache	7	0.8	2	0
Dysgeusia[g]	7	0	1.5	0

Abbreviation: BSoC, best standard of care.
[a]Peripheral edema includes peripheral edema, fluid retention, and fluid overload.
[b]Dry mouth includes dry mouth, aptyalism, and dry throat.
[c]Vomiting includes vomiting and retching.
[d]Abdominal pain includes abdominal pain, abdominal pain upper, abdominal discomfort, abdominal pain lower, abdominal tenderness, and gastrointestinal pain.
[e]Urinary tract infection includes urinary tract infection, cystitis, and cystitis bacterial.
[f]Acute kidney injury includes blood creatinine increased, acute kidney injury, renal failure, and blood urea increased.
[g]Dysgeusia includes dysgeusia and taste disorder.

Clinically relevant adverse reactions in < 5% of patients who received PLUVICTO plus BSoC included dry eye, vertigo, and pancytopenia (including bicytopenia).

Table 4: Select Laboratory Abnormalities (≥ 10%) That Worsened from Baseline in Patients With PSMA-positive mCRPC Who Received PLUVICTO Plus BSoC (Between Arm Difference of ≥ 5% All Grades) in VISION

Laboratory Abnormalities	PLUVICTO Plus BSoC[a]		BSoC[b]	
	All Grades (%)	Grades 3 to 4 (%)	All Grades (%)	Grades 3 to 4 (%)
Chemistry				
Decreased calcium	39	2.5	28	3
Decreased sodium	33	0.6[c]	23	1
Increased aspartate aminotransferase	28	1.1	18	1[c]
Increased creatinine	24	0.9[c]	14	0.5[c]
Increased potassium	24	0.6	18	0.5[c]
Increased sodium	11	0[c]	5	0[c]
Hematology				
Decreased lymphocytes	85	47	51	18
Decreased hemoglobin	63	15[c]	34	7[c]
Decreased leukocytes	56	7	22	2
Decreased platelets	45	9	20	2.5
Decreased neutrophils	28	4.5	9	0.5

Abbreviation: BSoC, best standard of care.
[a]The denominator used to calculate the rate for each laboratory parameter varied from 506 to 529 based on the number of patients with a baseline value and at least one post-treatment value.
[b]The denominator used to calculate the rate for each laboratory parameter varied from 194 to 198 based on the number of patients with a baseline value and at least one post-treatment value.
[c]No Grade 4 laboratory abnormalities worsening from baseline were reported.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

The safety and efficacy of PLUVICTO have not been established in females. Based on its mechanism of action, PLUVICTO can cause fetal harm *[see Clinical Pharmacology (12.1) in the full prescribing information]*. There are no available data on PLUVICTO use in pregnant females. No animal studies using lutetium Lu 177 vipivotide tetraxetan have been conducted to evaluate its effect on female reproduction and embryo-fetal development; however, all radiopharmaceuticals, including PLUVICTO, have the potential to cause fetal harm.

8.2 Lactation

Risk Summary

The safety and efficacy of PLUVICTO have not been established in females. There are no data on the presence of lutetium Lu 177 vipivotide tetraxetan in human milk or its effects on the breastfed child or on milk production.

8.3 Females and Males of Reproductive Potential

Contraception

Males

Based on its mechanism of action, advise male patients with female partners of reproductive potential to use effective contraception during treatment with PLUVICTO and for 14 weeks after the last dose *[see Clinical Pharmacology (12.1), Nonclinical Toxicology (13.1) in the full prescribing information]*.

Infertility

The recommended cumulative dose of 44.4 GBq of PLUVICTO results in a radiation absorbed dose to the testes within the range where PLUVICTO may cause temporary or permanent infertility.

8.4 Pediatric Use

The safety and effectiveness of PLUVICTO in pediatric patients have not been established.

8.5 Geriatric Use

Of the 529 patients who received at least one dose of PLUVICTO plus BSoC in the VISION study, 387 patients (73%) were 65 years or older and 143 patients (27%) were 75 years or older. No overall differences in effectiveness were observed between patients ≥ 75 years of age and younger patients. Serious adverse reactions occurred in 11% of patients ≥ 75 years of age and in 11% of younger patients. Grade ≥ 3 adverse reactions occurred in 40% of patients ≥ 75 years of age and in 31% of younger patients.

8.6 Renal Impairment

Exposure of lutetium Lu 177 vipivotide tetraxetan is expected to increase with the degree of renal impairment *[see Clinical Pharmacology (12.3) in the full prescribing information]*. No dose adjustment is recommended for patients with mild (baseline CLcr 60 to 89 mL/min by Cockcroft-Gault) to moderate (CLcr 30 to 59 mL/min) renal impairment; however, patients with mild or moderate renal impairment may be at greater risk of toxicity. Frequently monitor renal function and adverse reactions in patients with mild to moderate renal impairment *[see Dosage and Administration (2.4) in the full prescribing information]*. The pharmacokinetics and safety of PLUVICTO have not been studied in patients with severe (CLcr 15 to 29 mL/min) renal impairment or end-stage renal disease.

10 OVERDOSAGE

In the event of administration of a radiation overdosage with PLUVICTO, reduce the radiation absorbed dose to the patient by increasing the elimination of the radionuclide from the body by frequent micturition or by forced diuresis and frequent bladder voiding. Estimate the effective radiation dose that was applied and treat with additional supportive care measures as clinically indicated.

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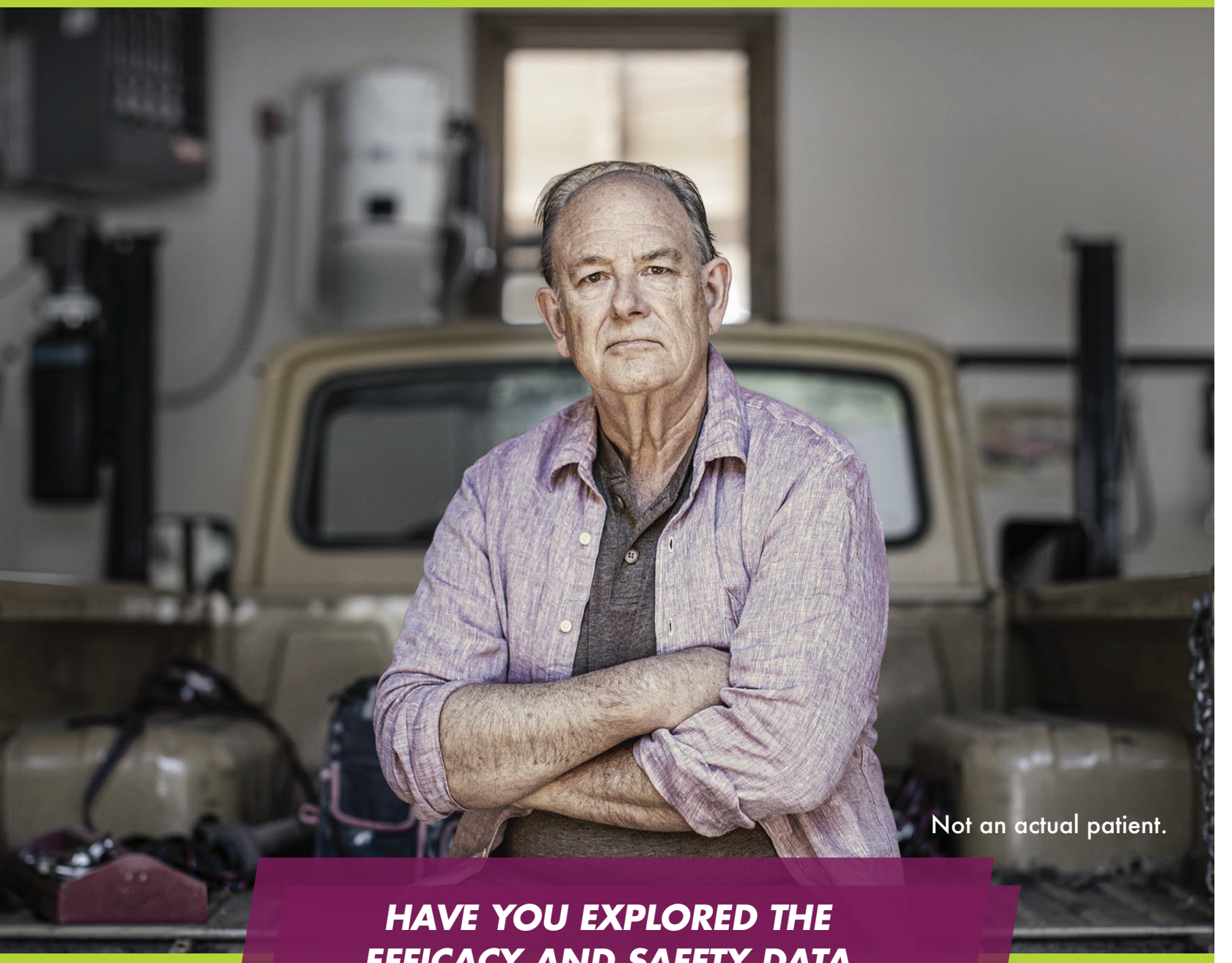

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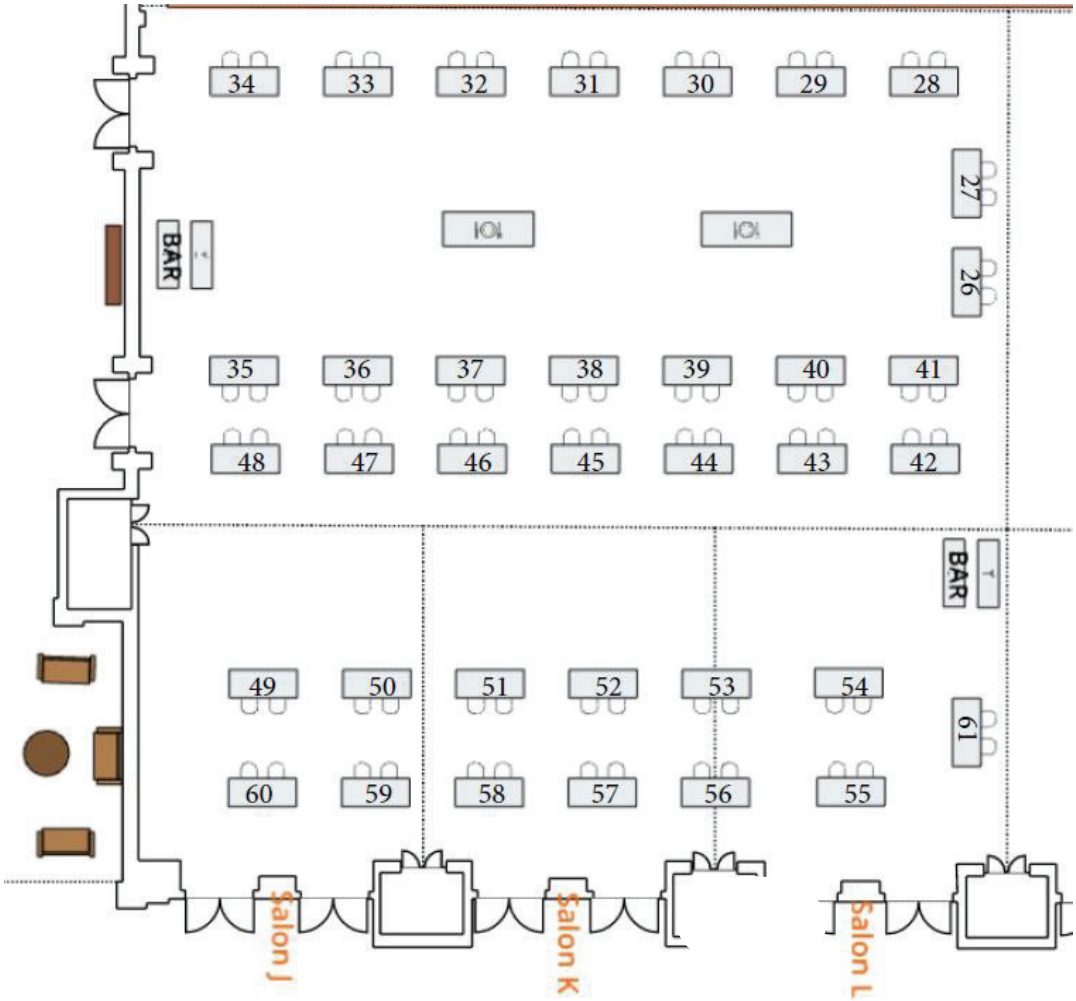

Industry Partner	Table #	Industry Partner	Table #
Accord BioPharma	45	mdxhealth	35
Advanced Accelerator Applications	29	Merck	26
AmerisourceBergen	50	Meriplex	28
Annexus Health	52	Millennia	55
Astellas Pharma and Pfizer Oncology	38	Modernizing Medicine	30
AstraZeneca	48	Molecular Testing Labs	32
Avenda Health	39	Myovant Sciences, Inc. and Pfizer, Inc.	49
Bayer	34	NextMed	60
Biote	43	Pacific Edge Diagnostics	56
Blue Earth Diagnostics, Inc.	37	Perineologic	51
Boston Scientific	47	Preveta	41
Cleveland Diagnostics	53	rater8	33
Dendreon	58	SCRUBS RRG	46
Exosome Diagnostics	59	Sun Pharmaceuticals, Inc.	40
Fellow	36	Teleflex Interventional Urology	27
Gemini Medical Technologies	57	UroGen Pharma, Inc.	42
Janssen Biotech, Inc.	31	Verity Pharmaceuticals	61
Lantheus	54	Vision RT	44

SYMPOSIUMS

BREAKFAST

SATURDAY, MAY 6, 2023
7:30AM – 8:30AM

A Clinical Review of NUBEQA® (darolutamide) Efficacy and Tolerability in Metastatic Hormone-Sensitive Prostate Cancer (mHSPC) in Combination With Docetaxel and in Non-Metastatic Castration-Resistant Prostate Cancer (nmCRPC)

Speaker: Tim Richardson, MD

LUNCH

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SATURDAY, MAY 6, 2023
12:00PM – 1:00PM

Clinical Profile of a PARP inhibitor for the Treatment of mCRPC

Speaker: Scott B. Sellinger, MD, FACS

SAVE THE DATE

2023 PROGRAMS

May 18-20, 2023
Prostate Cancer Academy (PCA)
Westin Irving Convention Center, Irving (Dallas), TX

November 2-4, 2023
LUGPA 2023 Annual Meeting
Disney's Yacht & Beach Club Resort, Orlando, FL

November 16-18, 2023
Bladder and Kidney Cancer Academy, Location TBA

2024 PROGRAMS

February 10-11, 2024
Regional Meeting
Grand Hyatt Vail, Vail, CO

March 1-2, 2024
The LUGPA 2024 Urology Resident Summit and Job Fair
Grand Hyatt DFW Hotel (International Airport), Dallas, TX

April 12-13, 2024
Regional Meeting
Nashville Renaissance, Nashville, TN

June 7-8, 2024
Regional Meeting
The Wynn, Las Vegas, NV

November 14-16, 2024
LUGPA 2024 Annual Meeting
Chicago Marriott Downtown
Magnificent Mile Hotel, Chicago, IL

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