



2019 Annual Meeting



ANAHEIM, CALIFORNIA
JUNE 22-25, 2019

www.snmmi.org/2019preview2

IN THIS ISSUE

The Guiding Light...

Learn about the Meeting theme and trailblazers who continue to inspire it.

200+ CE and Scientific Sessions

Get the full scope of what's being offered in Anaheim.

Don't Forget Your Mouse Ears

Learn about exclusive discounts available for Annual Meeting attendees!

Preview Magazine > Issue 2

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THE GUIDING LIGHT:

Nuclear Medicine & Molecular Imaging... Trailblazing Imaging Practice and Sciences

This year's meeting theme celebrates innovations in instrumentation and the application of that technology in the advancement of patient care. We encourage you to attend the plenary sessions to hear directly from the trailblazers representing just some of these amazing advancements, including:



Henry N. Wagner, Jr., MD Lectureship
Markus Schwaiger, MD

Dr. Markus Schwaiger is the Managing Medical Director of the Klinikum rechts der Isar, Technical University of Munich, Germany. His research portfolio reflects the development of PET from a research tool in cardiology to a world-wide accepted clinical standard procedure in oncology.



Hal Anger Lectureship
The Anger Principle "Trailblazed" the Way to
Total Body PET and Its Future Applications
Terry Jones, BSc, MSc, DSc, MD

Dr. Terry Jones is a world renowned medical physicist who has been involved in the development of the clinical research applications of cyclotron produced, positron emitting radionuclides. His most recent endeavors have been focused on the development of Total Body PET.

An astounding program of 200+ CE and scientific sessions focused on the latest developments, research, and clinical applications in nuclear medicine and molecular imaging awaits you in Anaheim.

- What new skill will you gain to work more efficiently?
- What new product or technology in the exhibit hall will revolutionize your practice?
- Which new professional connection will help solve a similar challenge?

Register today!

www.snmmi.org/2019preview2

SCHEDULE AT A GLANCE

SATURDAY June 22, 2019

6:30–9:00 am
Hot Trot 5K Run/Walk

7:30 am–3:00 pm
Categorical Seminars

8:00 am–4:45 pm
Nuclear Medicine Review Course (NMRC) – Day 1

8:00 am–4:15 pm
SNMMI-TS CE Courses

8:00 am–4:45 pm
Student Technologist Registry Review (STRR) – Day 1

9:00 am–4:45 pm
Educators Forum I & II

1:30–4:45 pm
SNMMI CE Courses

5:00–6:00 pm
Welcome Plenary Session

6:00–8:00 pm
Welcome Reception: Exhibit and Poster Hall Opening

8:00 pm–End
User Meetings

SUNDAY June 23, 2019

6:00–8:00 am
User Meetings

8:00 am–5:30 pm
Nuclear Medicine Review Course (NMRC) – Day 2

8:00–9:30 am
Opening Plenary Session: Henry N. Wagner Jr., MD, Lectureship

9:30 am–4:30 pm
Exhibit Hall

10:00 am–8:30 pm
Scientific & Educational Poster Hall

12:15–2:00 pm
Technologist Plenary Session & Awards Recognition

12:30–2:00 pm
Young Professionals Committee (YPC) Knowledge Bowl

12:30–6:15 pm
SNMMI CE Courses & Scientific Abstract Presentations

2:30–5:30 pm
Student Technologist Registry Review (STRR) – Day 2

2:45–4:45 pm
Educators Forum III

3:00–6:15 pm
SNMMI-TS CE Courses & Scientific Abstract Presentations

4:45–6:15 pm
Radiopharmaceutical Sciences Council (RPSC)/CMIIT Basic Science Summary Session

4:30–6:00 pm
Emerging Technologies Session (CMIIT) #1 (Non-CE)

6:30–8:30 pm
RPSC/CMIIT Poster Mixer

6:30 pm–End
User Meetings

MONDAY June 24, 2019

6:00–8:00 am
User Meetings

8:00–9:30 am
SNMMI Business Meeting and Special Plenary/Cassen Lectureship

9:00 am–6:00 pm
Scientific & Educational Poster Hall

9:30 am–4:30 pm
Exhibit Hall

10:00–11:30 am
Emerging Technologies Session (CMIIT) #2 (Non-CE)

10:00 am–4:30 pm
SNMMI-TS CE Courses

10:00 am–6:15 pm
SNMMI CE Courses & Scientific Abstract Presentations

2:00–3:00 pm
Young Investigators (YIA) and Young Professionals Committee (YPC) Awards Ceremony

3:00–4:30 pm
“Meet the Author” Session I

3:00–7:00 pm
Emerging Technologies Session (CMIIT) #3 (Non-CE)

3:00–4:30 pm
Computer and Instrumentation Basic Science Summary Session

4:45–6:15 pm
SNMMI-TS Business Meeting

6:00 pm–End
User Meetings

TUESDAY June 25, 2019

6:00–8:00 am
User Meetings

8:00 am–2:00 pm
SNMMI-TS CE Courses

8:00 am–4:30 pm
CT and MRI Case Reviews

8:00 am–4:30 pm
SNMMI CE Courses & Scientific Abstract Presentations

9:00 am–5:00 pm
Scientific & Educational Poster Hall

9:30 am–3:00 pm
Exhibit Hall

3:00–4:30 pm
Scientific Poster Awards

3:00–4:30 pm
“Meet the Author” Session II

4:45–6:15 pm
Henry N. Wagner, Jr., MD Highlights Symposium

6:15–7:15 pm
Closing Celebration

7:15 pm–End
User Meetings

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SPEAKERS

SNMMI's Annual Meeting welcomes some of the top professionals in the field to lead an expansive educational program. Speakers include:

- Amanda Abbott, CNMT, RT(N) (CT), PET
- Anissa Abi-Dargham, MD
- Jonathan Adams, BS
- Adina Alazraki, MD
- Nathalie Lisa Albert, MD
- Adam Alessio, PhD
- Mouaz Al-Mallah, MD
- John K. Amartey, PhD
- Melissa Andrews, CNMT, PET, ARRT (CT)
- Javier Arbizu, MD, PhD
- Martin Auerback, MD
- Anca Avram, MD, FACNM
- Ali Azhdarinia, PhD
- Elizabeth Bailey, PhD
- Dale Bailey, PhD
- Ethan Balkin, PhD
- Betsy Ballard, MD
- Twyla Bartel, DO, MBA, FACNM
- Henryk Barthel, MD, PhD
- Scott C. Bartley, MD
- Timothy Bateman, MD
- Jean-Mathieu Beaugerard, MD, MSc, FRCPC
- Muhammad Beg, MD
- Fatemeh Behnia, MD
- Frank Bengel, MD
- Gholam Reza Berenji, MD, ACNM
- Daniel S. Berman, MD
- Larry Blinkovitz, MD
- Fernando Boada, PhD
- Ronald Boellard, PhD
- John P. Bois, MD
- Wesley E. Bolch, PhD
- Norman Bolus, MSPH, CN-MT, FSNMMI-TS
- Salvador Borges-Neto, MD
- Crystal Botkin, PhD, MPH, CNMT, PET,
- Jamieson B. Bourque, MD, MHS
- Stephen R. Bowen, PhD
- Adam Brown, BS, CNMT, RT(N), PET
- Lance Burrell, MS, CNMT, PET, RT(CT)
- John R. Buscombe, MD, FRCP
- Weibo Cai, PhD
- Kendra Cameron, MD
- Luca Camoni, NMT, MSc
- Rusell Caprioli, DPM
- Richard E. Carson, PhD
- Shawn S. Carter, MD
- Denise Casey, MD
- Paniithaya Chareonthaitawee, MD
- Delphine L. Chen, MD
- Wengen Chen, MD, PhD
- Xiaoyuan (Shawn) Chen, PhD
- Steve Cho, MD
- Harry Chugani, MD
- Peter Clark
- Bonnie Clarke, BS
- Erica J. Cohen, DO, MPH, FACNM
- Patirck M. Coletti, MD, FACNM, FSNMMI
- Maria Costello, BS, CNMT, NCT
- Elpida S. Crawford, CNMT
- Donna J Cross, PhD
- Geoffrey Currie, PhD BPharm MMRS CNMT
- Molly Curtin
- Cathy Sue Cutler, PhD
- Simindokht Dadparvar, MD, FACNM, FACR
- Said Daibes Figueroa, PhD
- Heike E. Daldrup-Link, MD
- Robert DeKemp, PhD
- E. Gordon DePuey, MD
- Marcelo F. Di Carli, MD
- David W. Dick, PhD
- Gary L. Dillehay, MD, FACNM, FACR, FSNMMI
- Vasken Dilsizian, MD
- Mary Disis, MD
- Yu-Shin Ding, PhD
- Sabina Dizdarevic, MD, PhD, FRCP
- John T. Doan, MD
- David J. Donnelly, PhD
- Sharmilla Dorbala, MD
- Alexander E. Drzezga, MD
- Lisa K. Dunnwald, CNMT
- Andrew J. Einstein, MD, PhD
- Georges N. El Fakhri, PhD, FSNMMI
- Shana Elman, MD
- Joseph R. England, MD
- Frederick H. Fahey, DSc, FSNMMI
- Mary Beth Farrell, MS, CNMT, NCT, FSNMMI-TS
- Michael D. Farwell, MD
- Darrell Fisher, PhD
- Peter Francis, MD
- Leonard M. Freeman, MD, FACNM, FSNMMI
- Kirk A. Frey, MD, PhD
- Sarah A. Frye, MBA, CNMT, PET, CCRP
- Jeff A. Galen, CNMT
- Norbert Galdikis, MD
- Christopher Galliford
- Sanjiv S. Gambhir, MD, PhD
- Ernest V. Garcia, PhD
- Andrew Gelman, PhD
- Joseph F. Germino, MD, PhD
- Lauren Gilbert, CNMT, RT(N) (CT)
- C. David Gillmore, EdD, CNMT, FSNMMI-TS
- Jamieson L. Gladson, MSRS, CNMT, RT(CT)
- Gopinath Gnanasegaran, MD
- Michael M. Graham, PhD, MD, FSNMMI
- Ravinder K. Grewal, MD, FACNM
- Seza A. Gulec, MD
- Christer Halldin, PhD
- Cameron Hassani, MD
- Mathieu Hatt, PhD
- Andrew Hendifar, MD, MPH
- Jose Miguel Herndez Pampaloni, MD, PhD
- John M. Hoffman, MD
- Duane A. Hollier, Sr., CNMT, ARRT(N), BS
- Zhao Hong
- Thomas A. Hope, MD
- Andrew G. Horti, PhD
- Eric Hostetler, PhD
- Simon Hughes, MD
- Edward A. Hulten, MD
- Fabien Hyafil, MD, PhD
- Mark C. Hyun, CNMT, NCT, RT, FASNC
- Kazunari Ishii, MD, PhD
- Ora Israel, MD, FSNMMI
- Kimberly Kerrylin Jackson, CNMT, RT(N)(MR)
- Hossein Jadvar, MD, PhD, FACNM, FSNMMI
- Sanjay K. Jain, MD
- Diwarkar Jain, MD, FSNMMI
- Floris P. Jansen, PhD
- Charlotte D. Jeffers, RPh
- Charlotte Denise Jeffers, PharmD
- Richard B. Johnson, MD
- Sarah Johnson, MBA, CNMT, NCT, FSNMMI-TS
- Hyan Jouni, MD
- Peter V. Kamvosoulis, BS, PET, RT(N)(CT)(MR)
- S.Cheenu Kappadath, PhD
- Ayse Tuba Karagulle Kendi, MD
- Joel S. Karp, PhD
- Ravindra K. Kasliwal, PhD
- Zohar Keidar, MD, PhD
- Kimberly A. Kelly, PhD
- Adam L. Kesner, PhD
- Amir H. Khandani, MD
- Michael A. King, PhD, DABR
- John Kirkwood, MD
- Michael V. Knopp, MD, PhD
- Robert A. Koeppel, PhD
- Ran Klein, PhD
- Susanne Kossatz, PhD
- Caitlin Kubler
- Rakesh Kumar, MD, PhD
- Arvind Kumar, MD
- Charles Kunos, MD, PhD

SPEAKERS

- Renaud La Joie, MD
- Susanne Landau, MD
- Abebayo Laniyonu, PhD
- Benjamin Larimer, PhD
- Roger Lecomte, PhD
- Daniel Lee, MD
- Gregoire LeGal, MD
- Craig S. Levin, PhD
- Quanzhen Li, PhD
- Chun Li, PhD
- Steven H. Liang, PhD
- Ruth Lim, MD
- Chi Liu, PhD
- Kevin London, FRACP, PhD
- Val J. Lowe, MD
- Cindi Luckett-Gilbert, MHA, CNMT, RSO, FSNMMI-TS
- Robert Henry Mach, PhD
- Josh Mailman, MBA
- M. Ben Major, PhD
- Mehran Makvandi, PharmD, BCNP
- Saurabh Malhotra, MD, PhD
- April Mann, MBA, CNMT, NCT, RT(N)
- Maurizio Franco Mariani, MD, PhD
- Donna Mars, CNMT, NCT
- Louis Marzella, MD, PhD
- Osama R. Mawlawi, PhD
- Jonathan McConathy, MD, PhD
- Alan McMillian, PhD
- Denise Merlino, CNMT, CPC, MBA, FSNMMI-TS
- Darlene Metter, MD, FACR
- Mark Michalski, MD
- Enrique Michelotti, PhD
- Miles Miller, PhD
- Edward J. Miller, MD, PhD, FASNC, FACC
- Steven W. Millward, MD
- Satoshi Minoshima, MD, PhD
- Akiva Minta, MD, PhD
- Ashley Elizabeth Mishoe, PharmD
- Erik Mittra, MD, PhD
- Romina Mizrahi, PhD
- Rustain L. Morgan, MD
- Thomas M. Morneau, CNMT
- Karina Mosci, MD
- James Mountz, MD, PhD
- Venkatesh L. Murthy, MD, PhD
- Helen Nadel, MD
- Niclolle Nardecchia, MBA, CNMT, PET, RT(CT)(MR)
- Elad Nevo, MS, RT(MR)(N)(CT), CNMT
- Thomas Ng, MD, PhD
- Yoshihiro Nishiyama, MD, PhD
- Nobyuuki Okamura, MD, PhD
- Robert Pagnanelli, BSRT(R)(N), CNMT, NCT
- Christopher J. Palestro, MD, FSNMMI
- Neeta Pandit-Taskar, MD
- Marguerite T. Parisi, MD, MS Ed
- Arum Parthipun, MD
- Dakshesh Patel, MD
- Lisa L. Patrick, BSRS, RT(N), NCT, CT
- Soren Mattsson PhD, PhD
- Vladimir Ponomarev, MD, PhD
- James A. Ponto, MS, RPh, BCNP
- Jennifer L. Prekeges, MS, CNMT, FSNMMI-TS
- Julie C. Price, PhD
- John O. Prior, PhD, MD
- Daniel Pryma, MD
- Darko Pucar, MD, PhD
- Ilan (Eugenii) Rabiner, PhD
- Meera Raghavan, MD
- Arman Rahmim, PhD
- Joseph Rajendran, MD
- Janet S. Reddin, PhD
- Brittany Robinson, NMS
- Melissa Rodnick, PhD
- Elizabeth C. Romero, RT(N)(CT), FSNMMI-TS
- Lessa Ann Ross, CNMT, PET, RT(N)(CT)
- David Rotsch, PhD
- Steven M. Rowe, MD, MSPH
- Lynne T. Roy, MBA, CNMT, FSNMMI-TS
- Terrence D. Ruddy, MD
- Mehran M. Sadeghi, MD
- Brenda Sandmaier, MD
- Andrea Santos, MSc
- Machaba Michael Sathekge, MD, PhD
- Chitra Saxena, MPH
- Heinrich R. Schelbert, MD, PhD
- Thomas Hellmut Schindler, MD
- Jeffrey Schmall
- David M. Schuster, RT(N)(CT), FSNMMI-TS
- Peter J.H. Scott, PhD
- George M. Segall, MD, FACNM, FSNMMI
- Victor Seghers, MD, PhD
- Svetlana Selivanova, PhD
- Mark A. Sellmyer, MD, PhD
- Marc Seltzer, MD
- Georges Sgouros, PhD
- Lauren Shanbrun, MS, CNMT, RT(N)(CT)
- Lalitha K. Shankar, MD, PhD
- Akash Sharma, MD, MBA
- Anthony F. Shields, MD, PhD
- Steven Shoner, PhD
- Barry L. Shulkin, MD, MBA
- Anthony J. Sicignano, BS, CNMT, RT(N), FSNMMI-TS
- Barry A. Siegel, MD, FSNMMI
- Daniel H. Silverman, MD, PhD
- Albert J. Sinusas, MD, FACC, FAHA
- Mark Slifstein, PhD
- Piotr J. Slomka, PhD
- Gary R. Small, PhD, MB, ChB, MRCP
- Kiran K. Solingapuram Sai, PhD
- Lilja B. Solnes, MD
- Prem Soman, MD, PhD
- Michael G. Stabin, PhD
- Sasha E. Stanton, MD, PhD
- Lisa J. States, MD
- Stanley H.Y. Stern, PhD
- Rathana M. Subramaniam, MD, PhD, MPH, FACNM, FSNMMI
- John J. Sunderland, PhD, MBA
- Julie L. Sutcliffe, PhD, FSNMMI
- Miwako Takahashi, MD, PhD
- Amol M. Takalkar, MD, MS, MBA, FACNM
- Gilles D. Tamagnan, PhD
- Hideki Tashima, PhD
- Giorgio Testanera,
- James T. Thackeray, PhD
- Kathy S. Thomas, MHA, CNMT, PET, FSNMMI-TS
- Christopher Thome, MD
- Stephanie L. Thorn, PhD
- Nushin Todd, MD, PhD
- Khoa Tran, MD
- Vera Tsatkin, MS, CNMT, ARRT(N)
- Mark Tulchinsky, MD, FACNM, CCD
- Jean-Luc C. Urbain, MD, PhD, CPE
- Tim Van den Wyngaert, MD, PhD
- Douglas Van Nostrand, MD
- Victor Villemagne, MD
- Nerissa Therese Viola-Villegas, PhD
- Mona M. Wahba, MD, MSM
- Richard L. Wahl, MD, FACNM
- Sue Jane Wang, PhD
- Michele F. Wanner, CNMT
- Ashley Ward, MD
- Kristen M. Waterstram-Rich, CNMT, FSNMMI-TS
- Wolfgang Weber, MD
- Richard Lawrence Weinburg, MD
- Ralph Weissleder, PhD
- David Weinreb, MD
- R. Glenn Wells, PhD
- Richard E. Wendt, III, PhD
- Jan M. Winn, MEd, RT(N), CNMT
- John Witkowski, President
- Dean F. Wong, MD, PhD
- Anna M. Wu, PhD
- Taiga Yamaya, PhD
- Dusty M. York, CNMT, PET, RT(N)(CT)
- Greg Zaharchuck, MD, PhD
- Jun Zhang, MD
- Katherine Zukotynski, BASc, MD, FRCP

CE SESSIONS

More than 125 CE sessions will be available at the SNMMI 2019 Annual Meeting, with the opportunity to earn more than 25 CE Credits. Sessions include:

Track	Saturday June 22, 2019	Sunday June 23, 2019	Monday June 24, 2019	Tuesday June 25, 2019
Anatomical Imaging				Head and Neck CT Case Review (Cases 1-13) Chest and Cardiac CT Case Review (Cases 14-25) Musculoskeletal CT Case Review (Cases 26-38) Abdomen and Pelvis CT Case Review (Cases 39-50)
Cardiovascular	Cardiovascular Molecular Imaging & Theranostics	Non-Invasive Evaluation of CAD in 2019 Cardiac Amyloidosis: Introduction and Applications	Nuts and Bolts of Myocardial Blood Flow: Clinical Applications Cardiovascular Boot Camp	Cardiac Image Quantification
Career Development/Leadership	Private Practice/Community Based Physicians	Management and Leadership in Nuclear Medicine and Molecular Imaging I Women in Nuclear Medicine Management and Leadership in Nuclear Medicine and Molecular Imaging II Tackling Diversified Clinical Management Questions Mental Health and Wellness in Nuclear Medicine	New Opportunities in Nuclear Medicine—Perspectives and Insights from Healthcare Career Paths in the Radiopharmaceutical Sciences Making the Transition from Training to the Nuclear Medicine Workforce	Hermann Blumgart Award Lecture: Growing Research Opportunities in Cardiovascular Nuclear Medicine Early Career Professionals Committee Session
General Clinical Specialties	Cardiac PET Workshop CGNMC Lectureship Award Session Binary V/Q Scintigraphy in North America	Knowledge Bowl Barry Siegel Lecture: Correlative Imaging Using PET/CT and SPECT/CT; CIC Business with “Bites” Molecular and Radiologic Imaging of Common and Uncommon Musculoskeletal Diseases Case-Based Total Body PET and Its Applications Tele Nuclear Medicine: The Success Stories History Committee Session	PET/CT Assessment Response V/Q Lung Imaging: Pulmonary Embolism and Beyond Best Clinical Practice ACMUI Update Session Diabetic Foot Osteomyelitis: Diagnosing and Monitoring Treatment with Imaging Case-Based Approach to Challenging Cases in Nuclear Medicine Technological Advances in PET/CT Imaging: What you Really Need to Know Valk Award Lecture: PET in Prostate Cancer—Frontierland and Tomorrowland	Hermann Blumgart Award Lecture: Growing Research Opportunities in Cardiovascular Nuclear Medicine Early Career Professionals Committee Session
Instrumentation and Data Analysis	Nuts and Bolts – State of the Art PET/CT: Physics, Instrumentation, Performance and Clinical Application Innovation in PET Instrumentation Enable by Made-in-Japan Technologies			

CE SESSIONS

Track	Saturday June 22, 2019	Sunday June 23, 2019	Monday June 24, 2019	Tuesday June 25, 2019
Molecular Targeting Probes	Target Identification Nuts and Bolts: Using Lutetium-177 Dotatate	Molecular Imaging for Immunotherapy Molecular Imaging in Drug Development New PET Radiopharmaceuticals—Read with the Experts	Cancer Immunotherapy: Current Status and Future Directions Current State of Development of New Theranostic Agents Hoffman Award Lecture Michael J. Welch Award Presentation and Lecture US Regulatory Pathways for Diagnostic and Therapy Radiopharmaceuticals Dosimetry Methods and Dose/Effects Relationships Practical Radiopharmaceutical Dosimetry	Radioisotope Production for Theranostics Motion Correction: Basic Technology and Clinical Applications Nuts and Bolts: How Do I Get New Imaging Agents at My Site? Nuts and Bolts of Ga-68 Therapy Joint SNMMI/AAPM Symposium—Bridging Nuclear Medicine and Radiation Therapy towards Precision Oncology AI for Data Sciences
Neurosciences	Advancements in Brain Tumor Imaging	Can We Use Quantitative PET in Clinical Practice?	Brain Imaging Read with the Experts	What Nuclear Medicine Physicians Need to Know About Epilepsy Implementation of the New Neuroimaging Framework for the Diagnosis of Alzheimer’s Disease
Oncology and Therapy	Prostate Cancer Nuts and Bolts: Diagnosis and Therapy New Perspectives in the Diagnostic Approach of Neuroendocrine Tumors	Differentiated Thyroid Cancer Theranostics Practicum Present and Future of PRRT in the Treatment of Neuroendocrine Tumors Radiation Dosimetry in Nuclear Oncology Practice—Striking a Balance in an Era of Theranostics	Current Uses of MIBG and New Directions Saul Hertz Award Symposium: The Atomic Cocktail of Radioiodine Users in Precision Oncology The Era of PRRT: Personalization, Integration and Future Perspectives Neuroendocrine Tumor Diagnosis and Therapy	Joint NANETS/SNMMI Session Theranostics 101: Practical Clinical Aspects Joint ATA/SNMMI Session PET Melanoma in the Age of Immunotherapy (ANZSNM) Imaging and Therapy for Thyroid Cancer—The Theranostics Paradigm
Pediatrics			Advanced Pediatric Imaging Pediatric PET/MR	Pediatric Read with the Experts Session
Technologist-Focused	Quality in Nuclear Medicine General Nuclear Medicine Theranostics	Leadership and Mentoring: Becoming a Positive Role Model Radiopharmacy/Radiation Safety I Radiopharmacy/Radiation Safety II ARRT Updates Cardiovascular Bootcamp I	Lu-177 Dotatate Therapy: A Radiologist and Technologist Perspective Coding Update 2019 and Beyond Differentiated Thyroid Cancer Management and Therapy Update Updates on USP 825 and Isotope Production Nuclear Medicine’s Role in Pathology Across the Globe JNMT—Share Your Experience PET Jeopardy! Do you Know Your Stuff? Nuts and Bolts on New Radionuclide Therapies Simple Tips and Dirty Tricks for Writing a Manuscript Ethics and You Women in Nuclear Medicine	MRI PET/CT: Politics and the Future Molecular Imaging in a Big Picture Cardiac PET in 2019 The Evolution of Education for the NMT—Past, Present, and Future The Business of Molecular Imaging—Quality Improvement and Outcome Improvement Techniques Beyond Routine Brain Imaging

As of March 31, 2019. Please note, new session information is being added daily. Visit www.snmmi.org/2019Preview2 for the most up-to-date session listings.

SCIENTIFIC SESSIONS

The SNMMI 2019 Annual Meeting's scientific program includes 80 scientific sessions featuring 740 oral abstract presentations, and a scientific poster hall with more than 1,100 posters.

Track	Saturday June 22, 2019	Sunday June 23, 2019	Monday June 24, 2019
Cardiovascular	Metabolism & Molecular Imaging (Basic Science)	Cardiovascular YIA Sympsoium Advances in Clinical Utility of Myocardial Blood Flow Quantification	Perfusion & Flow Quantification (Basic Science) Improving Prognostication from Cardiac Nuclear Imaging Infiltrative Cardiomyopathies & Infection Imaging
General Clinical Specialties	Renal/Hypertension	Musculoskeletal Pediatrics	Outcomes/Infectious Disease/ Pulmonary II Outcomes/Infectious Disease/ Pulmonary II Gastroenterology
Molecular Targeting Probes	Center for Molecular Imaging Innovation & Translation (CMII) YIA Symposium	Novel Radiometal & Fluorine-18 Chemistry Radiopharmaceutical Sciences (RPSC) YIA Symposium	Radiopharmacy: GMP Synthesis and Quality Control Improvements Dosimetry Novel Radiochemistry for Cancer Applications
Neurosciences	Brain Imaging Council YIA Symposium	Neurosciences-Basic Science I Neurosciences-Basic Science II	Amyloid & Tau PET Novel Brain Imaging Targets Brain PET/MRI
Oncology, Basic	PSMA Based Agents (Oncology, Basic Science)	Center for Therapy Excellence YIA Symposium Technical Advances & Quantification	Oncology, Basic & Translation I (Basic Science) Oncology, Basic & Translation II (Basic Science) Oncology, Basic & Translation III (Basic Science)
Oncology, Clinical	Multiple Myeloma	Lung Cancer I: Molecular Biomarkers & Molecular Imaging Signatures Lung Cancer II: Targeted Therapies, Response to Treatement, and Prognosis	GI-Colorectal, Liver, Esophageal Other Solid Tumors (Diagnosis) Head & Neck
Physics, Instrumentation, Data Sciences	Image Generation: ECT & CT	Physics, Instrumentation & Data Sciences YIA Symposium Image Generation: Quantitative PET/MR	PET Image Quality (Image Generation) New System Design & Emerging Technology I (Instrumentation) Image Quality & Quantitative Imaging (Instrumentation)

SCIENTIFIC SESSIONS

As of March 31, 2019. Please note, new session information is being added daily. Visit www.snmmi.org/2019Preview2 for the most up-to-date session listings.

Track	Tuesday June 25, 2019
Cardiovascular	Vulnerable Plaque & Innervation Imaging
General Clinical Specialties	NATs, BAT & All That Thyroid & Para-Thyroid Therapy Concepts I: Endocrinology Therapy Concepts II: Endocrinology
Molecular Targeting Probes	Preclinical Probes for Cardiovascular Preclinical Probes for Neuroimaging Preclinical Probes for Oncology I Preclinical Probes for Oncology II
Oncology, Basic	Translational Iamge Guided (Oncology, Basic)
Oncology, Clinical	Other Solid Tumors/Hematologic Malignancies I (Clinical) GI-Pancreatic & Neuroendocrine (Oncology, Clinical) Other Solid Tumors/Hematologic Malignancies II (Clinical) Gynecological Cancers Breast Cancer: Novel Tracer & Practice Advances (Oncology, Clinical) Lymphoma/Leukemia Sarcoma/Melanoma (Oncology, Clinical)
Physics, Instrumentation, Data Sciences	Dynamic & Whole-Body PET (Data Management) PET: quantitation & Reconstruction (Image Generation) New System Design & Emerging Technology II (Instrumentation) Machine Learning in NM Imaging II: Attenuation Correction & Image Enhancement (Data Sciences) Brain Imaging (Data Management)

Scientific Papers and Posters

Attend scientific sessions featuring oral and poster presentations by authors of accepted abstracts. Oral sessions are 90 minutes in duration and include up to 7 presentations per session with sufficient time allotted to answer questions from attendees, while poster sessions offer similar content with flexible viewing times. Investigators will be on-hand during the “Meet the Author” poster sessions to discuss their research.

Poster Hall Mixer

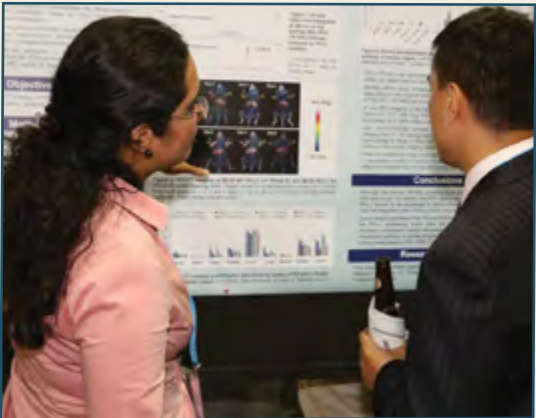
The Radiopharmaceutical Sciences Council (RPSC) and the Center for Molecular Imaging Innovation and Translation (CMII) invite you to attend the Annual Poster Mixer. This popular event is your opportunity to view hundreds of scientific posters, interact with authors, and build your network!

Poster Awards

At the start of the Tuesday “Meet the Author” poster session, poster finalists (1st, 2nd, and 3rd place winners) for scientific tracks, as well as educational exhibits, will be recognized for their work. Certificates will be presented to each finalist by the Chair of the Scientific Program Committee, and each winning poster will be identified by a prize ribbon affixed to the poster board.

International Best Abstract Awards

More than 60 countries are represented each year among the scientific abstracts featured during the annual meeting. SNMMI will again recognize the best scientific abstract from each submitting country.



THE PARK AFTER DARK

It's easy to feel wiped out after a day full of learning and networking but hang in there! Some of the best Disneyland® Park attractions take place after sunset.

Continue the Magic with specially priced tickets to Disneyland®

Learn more at:
www.snmml.org/AM_ears

Discounts are available exclusively for Annual Meeting attendees.



► At Disneyland® Park

Remember...Dreams Come True. Fireworks Spectacular Narrator Julie Andrews takes you on an amazing journey through the various lands of Disneyland® for one of the park's best-loved fireworks extravaganzas of all time: Remember...Dreams Come True. This dazzling 16-minute spectacular first delighted park visitors as the evening highlight of the 50th anniversary of Disneyland® in 2005 and returned in 2017 with all your favorite songs and familiar phrases from some of the most popular attractions at Disneyland®, past and present. From the beloved melody of "When You Wish Upon a Star," to the Haunted Mansion's mischievous "Grim, Grinning Ghosts," to the instantly recognizable and iconic theme from "Star Wars," the skies over Disneyland® come alive each night with a dazzling array of fireworks, flames and lasers to create memories you and your family will cherish for years to come!

► All Aboard

This summer, the classic Disneyland Railroad reopens to offer guests a relaxing 18-minute ride around the park. Originally opened in 1955, the Disneyland Railroad continues to be one of the park's most popular attractions, carrying passengers through the Grand Canyon, a prehistoric landscape complete with life-size dinosaurs, and the depths of Splash Mountain to one of four convenient stops within the park: Main Street, U.S.A., Tomorrowland, New Orleans Square or Mickey's Toontown – all on one of five restored, working narrow-gauge trains.

► Fantasmic! Returns to Ignite the Night

This summer, the skies over Rivers of America will once again come alive with the sights and sounds of Mickey's imagination as Fantasmic!, the parks' most beloved nighttime spectacular, returns! Watch Mickey use the power of love to defeat classic Disney villains during this one-of-a-kind cacophony of music, lasers, high-resolution digital film sequences, pyrotechnics and fiber optics leading up to the spectacular finale featuring a massive, 45-foot fire-breathing dragon!

courtesy of visitanahaim.org

NETWORKING

In addition to close to 200 CE and scientific sessions, the SNMMI Annual Meeting is your chance to meet face-to-face with your colleagues from across the globe. Be sure to make time to attend these great events and networking opportunities throughout the meeting!

► Saturday Evening Opening Ceremony

Taking place just prior to the Welcome Reception in the Exhibit Hall, you'll get an overview of the meeting, learn about sunny southern California, the host city of Anaheim, and how to get the most out of your visit. You'll also hear from this year's highlight country about the latest research and innovations happening in Canada.

► "Drink and Think"

These informal gatherings at local pubs and bars on Monday evening will be organized around particular areas of interest. This will give you an opportunity to relax with colleagues and new friends to discuss issues of common interest.

► Plenary Sessions and Henry N. Wagner, Jr., MD Highlights Symposium

These must-attend events highlight keynote speakers, significant awards and accomplishments, the SNMMI business meeting, installation of the new SNMMI president, a synopsis of research during the Annual Meeting, announcement of the Image of the Year and much, much more.

► Exhibit/Poster Hall Opening & Welcome Reception

Hosted by the SNMMI 2019 Annual Meeting Exhibitors

Packed with the latest trends and technology related to the fields of molecular imaging and nuclear medicine; don't miss your first chance to network with thousands of industry colleagues, industry leaders, and representatives from major manufacturers in the Exhibit Hall. The Exhibit Hall Grand Opening is the perfect kick-off event to four days of learning and science! Enjoy hors d'oeuvres, drinks, and music at this must-attend event!

► "On to New Orleans" Celebration

Join your colleagues and the SNMMI leadership following the Henry N. Wagner, Jr., MD Highlights Symposium, for a special toast to help kick off the countdown to the SNMMI 2020 Annual Meeting in New Orleans, Louisiana!



5th Annual "Hot Trot 5K" Run/Walk

Proceeds benefit the SNMMI-TS Professional Development and Education Fund, supporting the advancement of molecular and nuclear medicine technologists. A portion of registration proceeds will also support Project Access, providing low income families the tools needed to break the cycle of poverty. Exercise your body before you exercise your brain! Sign up today.

Sponsorship opportunities are also available. Visit www.snmml.org/HotTrot5K for info.

THE SNMMI 2019 EXHIBIT HALL

Explore the latest technologies, witness ground-breaking new products and services, and connect with more than 165 top industry suppliers ready to help furnish your organization with the tools and equipment needed to best serve you and your patients.

6th Theranostics World Congress 2021
Absolute Imaging Solutions
ABX Advanced Biochemical Compounds
ABX-CRO Advanced Pharmaceutical Services
Actinium Pharmaceuticals
Advanced Accelerator Applications
Advanced Cyclotron Systems, Inc.
Advanced Mobility by Kentucky Trailer
AirNet II, LLC
Alzheimer's Association
American College of Nuclear Medicine (ACNM)
American College of Radiology (ACR)
American Society of Nuclear Cardiology (ASNC)
AMICI, Inc.
AnazaoHealth Corporation
ANMI SA
The American Registry of Radiologic Technologists (ARRT)
Asia Oceania Federation of Nuclear Medicine and Biology (AOFNMB)
Association of Imaging Producers & Equipment Suppliers (AIPES)
Australian and New Zealand Society of Nuclear Medicine (ANZSNM)
Astellas Pharma US
Bayer - Radiology
Bayer Xofigo
BC Technical, Inc.
Becquerel & Sievert Co., Ltd

Best Cyclotron Systems, Inc.
Biodex Medical Systems, Inc.
BioLaurus Inc.
Blue Earth Diagnostics, Inc.
Board of Pharmacy Specialties (BPS)
Bracco Diagnostics
Bruker BioSpin
Cambridge Isotope Laboratories Inc.
Canadian Nuclear Laboratories
Canon Medical Systems USA, Inc.
Capintec, Inc.
Cardinal Health
Cardiovascular Imaging Technologies, LLC
CDL Nuclear Technologies
Center of Molecular Research
Certus International, Inc.
CHEMATECH
China Isotope & Radiation Corporation (CIRC)
Chinese Society of Nuclear Medicine
Clarity Pharmaceuticals
CMR Molecular Imaging
Comcer Group
Crystal Photonics GmbH
Curium
Cyclomedica Australia PTY LTD
Cyclomedical International, Inc.
Data Spectrum Corporation
Digirad
DOSIsoft
ec² Software Solutions

Eckert & Ziegler Isotope
Eckert & Ziegler Radiopharma
Eisai Inc.
Facet Life Sciences, Inc.
FORCE
GE Healthcare
Global Morpho Pharma
Hermes Medical Solutions, Inc.
Hidex Oy
Highlight Country Booth – Canada
Huayi Isotopes Company
IBA S.A.
ImaginAb, Inc.
Inter Medical Medizintechnik GmbH
Intersocietal Accreditation Commission (IAC)
INVIA Medical Imaging Solutions
Invicro
Inviscan SAS
Ionetix Corporation
Iotron Medical Inc.
iPHASE technologies
Ipsen Biopharmaceuticals, Inc.
IQ Medical Services
ISOFLEX USA
isoSolutions Marketing & Management Inc.
Iso-Tex Diagnostics, Inc.
Cyclomedical International, Inc.
Data Spectrum Corporation
Digirad
DOSIsoft
ec² Software Solutions

LabLogic Systems Limited
Lantheus Medical Imaging, Inc.
Life Molecular Imaging
Lucerno Dynamics, LLC
Lung Cancer Alliance
Macrocyclics
MarShield Radiation Protection Products
Medi/Nuclear Corporation, Inc.
MedImage, Inc.
Mediso Medical Imaging Systems Ltd.
MedTrace Pharma
MiE America Inc.
MIFTEC Laboratories, Inc.
MLabs
MIM Software Inc.
Mirada Medical
Modern Nuclear
MOLECUBES NV
Molecular Targeting Technologies, Inc.
MR Solutions Ltd.
MultiFunctional Imaging LLC
NorCal CarciNET Community
NorthStar Medical Radioisotopes, LLC
Nuclear Imaging Services, LLC
Nuclear Medicine Technology Certification Board (NMTCB)
Nuclear Shields
NUCMEDCOR
Oncidium Foundation
Oncovision Inc.
ORA – NEPTIS
Pacer Air Freight

THE SNMMI 2019 EXHIBIT HALL

PETNET Solutions
Pharmalucence
Philips
Pinestar Technology, Inc.
PMB ALCEN
PMOD Technologies LLC
Prescient Imaging
Progenics Pharmaceuticals, Inc.
Radiation Shielding Inc.
RadioMedix INC
RadQual Global Sources
Rotem Industries
SCINTOMICS Molecular (att)
Applied Theranostics Technologies GmbH
Segami Corporation
SEDECAL Molecular Imaging
Sirona Complete Care
Shandong Madic Technology Co., Ltd.
Siemens Medical Solutions USA
Society of Nuclear Medicine, India
SOFIE
South West Exposures
Southern Scientific
Southwestern Imaging Systems & Service (SWISS)
Spectrum Dynamics Medical, Inc.
Springer
Subtle Medical, Inc.
Sumitomo Heavy Industries, Ltd.
Sylvia Fedoruk Canadian Centre for Nuclear Innovation
SynterMed, Inc.
Synihra GmbH
Taiyo Nippon Sanso

Corporation
Telix Pharmaceuticals
Tema Sinergie S.P.A.
Theragnostics, Inc.
Thinking Systems Corporation
ThyCa: Thyroid Cancer Survivors' Association, Inc.
TransLite, LLC
Trasis
Triskem International
Tru-Motion Products
U.S. National Cancer Institute Radiation Epidemiology Branch
United Imaging Healthcare
Universal Medical Resources, Inc.
UPPI, LLC
US DOE Isotope Program
Varian Medical Systems
Von Gahlen International, Inc.
Washington University Medical School, Mallinckrodt Institute of Radiology
Wolfmet
Wolters Kluwer
WomenHeart
World Association of Radiopharmaceutical and Molecular Therapy (WARMTH)
World Federation of Nuclear Medicine and Biology (WFNMB)
World Molecular Imaging Society (WMIS)
Yantai Dongcheng Pharmaceuticals Group Co., Ltd.
Zionexa
Current Exhibitors
(as of March 28, 2019)

EXHIBIT HALL EVENTS

Exhibit/Poster Hall Opening & Welcome Reception—Saturday, June 22 | 6:00–8:00 pm

Hosted by the SNMMI 2019 Annual Meeting Exhibitors
Packed with the latest trends and technology related to the fields of molecular imaging and nuclear medicine; don't miss your first chance to network with thousands of industry colleagues, industry leaders, and representatives from major manufacturers in the Exhibit Hall. The Exhibit Hall Grand Opening is the perfect kick-off event to four days of learning and science! Enjoy hors d'oeuvres, drinks, and music at this must-attend event!

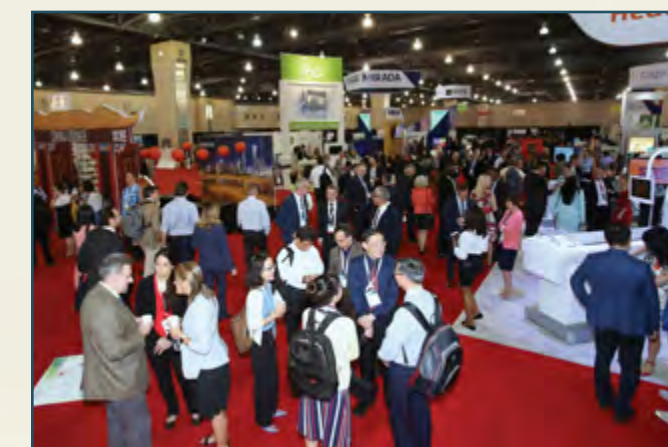
The Exhibit/Poster Hall will be open from Saturday evening to Tuesday afternoon during the SNMMI Annual Meeting.

Hot Spot Cash Drawings!

You will have **6 chances to win a \$300 CASH drawing**, simply by being in the right booth at the right time. Two drawings will take place each day during Dedicated Exhibit Hall Hours. Be sure you to listen for the announcement of the hot spot company name and booth number. If you're standing in that booth when the company name is called will be eligible to win the \$300 cash prize. Up to 20 companies will be participating – so be sure to visit them all!

Interactive Training Showcase

No CE credit will be available for these training sessions.
Learn directly from top suppliers. These thirty-minute, interactive training sessions on a variety of topics will take place on Sunday and Monday in the training showcase theater!





SNMMI
Hotel Locator Map



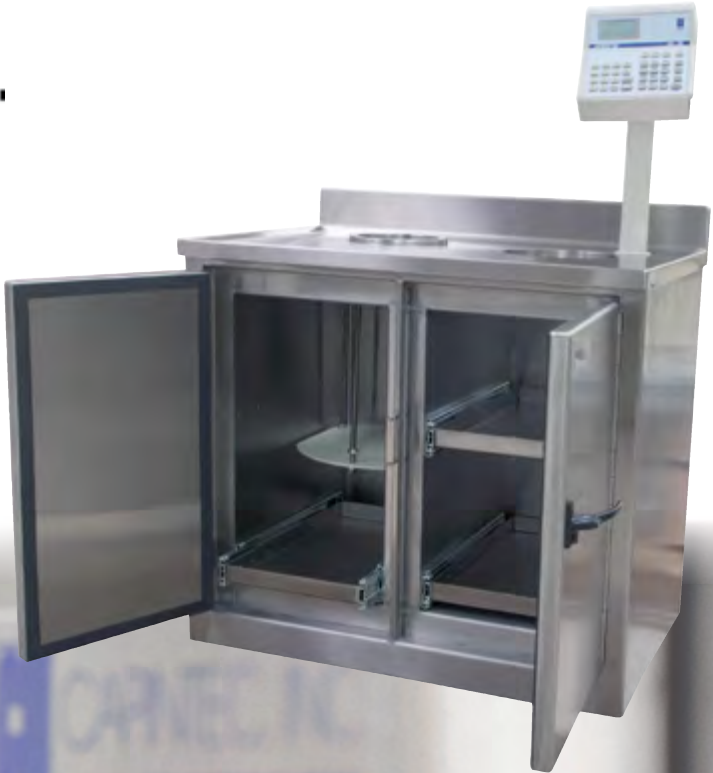
1. Anaheim Hotel
2. Anaheim Marriott
3. Hilton Anaheim
4. Hyatt House at Anaheim Resort/Convention Center
5. Red Lion Hotel Anaheim Resort
6. Sheraton Park Hotel at the Anaheim Resort
7. SpringHill Suites at Anaheim Resort/Convention Center

Hotels	Single/Double Occupancy*	Restaurants/Outlets	High Speed Basic Internet/night	Fitness Center (fee may apply)	Swimming Pool (Indoor/Outdoor)	Room Service	Comp Breakfast	Distance to Convention Center	Distance to John Wayne Airport - Orange County (SNA)	AAA Rating	Check-in/Out Time	Address
Anaheim Marriott	\$229	3	Comp	Yes	No/Yes	Yes	No	less than 1 block	14 miles	3	4 pm/12 pm	700 W Convention Way
Hilton Anaheim (HQ)	\$229	2	Comp	Yes \$9	Yes/Yes	Yes	No	less than 1 block	14 miles	3	4 pm/12 pm	777 W Convention Way
Hyatt House at Anaheim Resort/Convention Center	\$219	2	Comp	Yes	No/Yes	No	Yes	1 block	14 miles	3	4 pm/12 pm	1800 S Harbor Blvd
Red Lion Hotel Anaheim Resort	\$174	1	Comp	Yes	No/Yes	No	No	2 block	14 miles	3	3 pm/11 am	1850 S Harbor Blvd
Sheraton Park Hotel at the Anaheim Resort	\$219	5	Comp	Yes	No/Yes	Yes	No	1 block	14 miles	3	4 pm/11 am	1855 S Harbor Blvd
SpringHill Suites at Anaheim Resort/Convention Center	\$214	2	Comp	Yes	No/Yes	No	Yes	less than 1 block	14 miles	3	4 pm/11 am	1801 S Harbor Blvd
The Anaheim Hotel *	\$179	2	Comp	Yes	No/Yes	Yes	No	5 block	14 miles	3	4 pm/1 am	1700 S Harbor Blvd

Some hotels will charge additional fees for more than two people to a room. Rates quoted are for one night and exclude taxes and additional fees.
*Hotel will provide SNMMI with complimentary transportation to and from the Anaheim Convention Center via Shuttle in 15 minute intervals throughout the program of the convention.

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Quality and attention to detail is what you expect from Capintec... and that's what you get. Manufactured using only the highest quality materials for a lifetime of reliability, the cabinet's sleek, modern appearance with smooth rounded corners will enhance any hot lab, nuclear medicine department, or PET facility. Capintec's lead-lined cabinetry is available in a multitude of configurations, and designed with your budget in mind.

For over 50 years, Capintec is the company you have relied on and trusted for all of your nuclear medicine product needs. Now, you can rely on Capintec quality for all of your lead-lined cabinetry and radiation shielding products!



Call to inquire about our new
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MAKE YOUR PLANS TO ATTEND!

Regular Meeting Registration† (Saturday-Tuesday)

Registration Type	Pre-Reg Registration Rates (on/before June 20, 2019)		Onsite Registration Rates (beginning June 21)	
	Member	Nonmember	Member	Nonmember
Physician	\$780	\$1,290	\$890	\$1,400
Scientist	\$780	\$1,290	\$890	\$1,400
Industry	\$780	\$1,290	\$890	\$1,400
Technologist	\$450	\$705	\$550	\$805
Laboratory Professional*	\$485	\$795	\$595	\$905
Emeritus–Physician/Scientist	\$350	n/a	\$460	n/a
Emeritus–Technologist	\$215	n/a	\$315	n/a
Resident or Post-Doctural Fellow*	\$230	\$380	\$340	\$490
Technologist Student*	No Charge	\$105	No Charge	\$205
Companion/Guest (16 yrs or older)	\$50		\$50	

* **Resident Nonmembers and Student Nonmembers** (Resident, Scientist In-Training, Medical/Graduate/Technologist Student) must submit a completed verification form. Technologist Student, Medical Student and Resident-In-Training fees do not include CE Credit. Residents-In-Transition do receive CE Credit. Technologist Students wishing to claim CE credit must register as a Technologist.

† **Regular Registration** does not include categoricals or specialty workshops. These events require an additional fee. **Weekend registration includes a categorical course with the exception of technologists who will receive additional CE course credit beginning Saturday afternoon.**

» Pre-Meeting Categorical Seminars– (Requires an additional fee unless you are a weekend attendee)

See the meeting website for details.
Saturday, June 22
Member Fee: \$150 | Nonmember Fee: \$200

» Specialty Workshops

- **The Nuclear Medicine Review Course**
Saturday-Sunday, June 22-23, 2019
Member Fee: \$200 | Nonmember Fee: \$300
- **The Student Technologist Registry Review and Mock Exam**
Saturday-Sunday, June 22-23, 2019
Fee: \$50



This is a rare moment.

Patients living with advanced **pheochromocytoma and paraganglioma** have never had a proven treatment option. **Until AZEDRA.**

AZEDRA® is **the first and only** FDA-approved treatment for patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy.

Learn more at www.AZEDRA.com/healthcare-providers

Indication

AZEDRA® (iobenguane I 131) is indicated for the treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy.

Important Safety Information

Warnings and Precautions:

- **Risk from radiation exposure:** AZEDRA contributes to a patient's overall long-term radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk for cancer. These risks of radiation associated with the use of AZEDRA are greater in pediatric patients than in adults. Minimize radiation exposure to patients, medical personnel, and household contacts during and after treatment with AZEDRA consistent with institutional good radiation safety practices and patient management procedures.
- **Myelosuppression:** Among the 88 patients who received a therapeutic dose of AZEDRA, 33% experienced Grade 4 thrombocytopenia, 16% experienced Grade 4 neutropenia, and 7% experienced Grade 4 anemia. Five percent of patients experienced febrile neutropenia. Monitor blood cell counts weekly for up to 12 weeks or until levels return to baseline or the normal range. Withhold and dose reduce AZEDRA as recommended in the prescribing information based on severity of the cytopenia.
- **Secondary myelodysplastic syndrome, leukemia, and other malignancies:** Myelodysplastic syndrome (MDS) and acute leukemias were reported in 6.8% of the 88 patients who received a therapeutic dose of AZEDRA. The time to development of MDS or acute leukemia ranged from 12 months to 7 years. Two of the 88 patients developed a non-hematological malignancy.
- **Hypothyroidism:** Hypothyroidism was reported in 3.4% of the 88 patients who received a therapeutic dose of AZEDRA. Initiate thyroid-blocking medications starting at least 1 day before and continuing for 10 days after each AZEDRA dose to reduce the risk of hypothyroidism or thyroid neoplasia. Evaluate for clinical evidence of hypothyroidism and measure thyroid-stimulating hormone (TSH) levels prior to initiating AZEDRA and annually thereafter.
- **Elevations in blood pressure:** Eleven percent of the 88 patients who received a therapeutic dose of AZEDRA experienced a worsening of pre-existing hypertension defined as an increase in systolic blood pressure to ≥ 160 mmHg with an increase of 20 mmHg or an increase in diastolic blood pressure to ≥ 100 mmHg with an increase of 10 mmHg. All changes in blood pressure occurred within the first 24 hours post infusion. Monitor blood pressure frequently during the first 24 hours after each therapeutic dose of AZEDRA.
- **Renal toxicity:** Of the 88 patients who received a therapeutic dose of AZEDRA, 9% developed renal failure or acute kidney injury and 22% demonstrated a clinically significant decrease in glomerular filtration rate (GFR) measured at 6 or 12 months. Monitor renal function during and after treatment with AZEDRA. Patients with baseline renal impairment may be at greater risk of toxicity; perform more frequent assessments of renal function in patients

with mild or moderate impairment. AZEDRA has not been studied in patients with severe renal impairment.

- **Pneumonitis:** Fatal pneumonitis occurred 9 weeks after a single dose in one patient in the expanded access program. Monitor patients for signs and symptoms of pneumonitis and treat appropriately.
- **Embryo-fetal toxicity:** Based on its mechanism of action, AZEDRA can cause fetal harm. Verify pregnancy status in females of reproductive potential prior to initiating AZEDRA. Advise females and males of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment with AZEDRA and for 7 months after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 4 months after the final dose.
- **Risk of infertility:** Radiation exposure associated with AZEDRA may cause infertility in males and females. Radiation absorbed by testes and ovaries from the recommended cumulative dose of AZEDRA is within the range where temporary or permanent infertility can be expected following external beam radiotherapy.

Adverse Reactions:

The most common severe (Grade 3–4) adverse reactions observed in AZEDRA clinical trials ($\geq 10\%$) were lymphopenia (78%), neutropenia (59%), thrombocytopenia (50%), fatigue (26%), anemia (24%), increased international normalized ratio (18%), nausea (16%), dizziness (13%), hypertension (11%), and vomiting (10%). Twelve percent of patients discontinued treatment due to adverse reactions (thrombocytopenia, anemia, lymphopenia, nausea and vomiting, multiple hematologic adverse reactions).

Drug Interactions:

Based on the mechanism of action of iobenguane, drugs that reduce catecholamine uptake or that deplete catecholamine stores may interfere with iobenguane uptake into cells and therefore interfere with dosimetry calculations or the efficacy of AZEDRA. These drugs were not permitted in clinical trials that assessed the safety and efficacy of AZEDRA. Discontinue the drugs listed in the prescribing information for at least 5 half-lives before administration of either the dosimetry dose or a therapeutic dose of AZEDRA. Do not administer these drugs until at least 7 days after each AZEDRA dose.

For important risk and use information about AZEDRA, please see Brief Summary of Prescribing Information on adjacent pages.

To report suspected adverse reactions, contact Progenics Pharmaceuticals, Inc. at 844-668-3950 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Reference: AZEDRA® prescribing information. New York, NY: Progenics Pharmaceuticals, Inc.; 08 2018.

AZEDRA® is a registered trademark of Progenics Pharmaceuticals, Inc. Trademarks, registered or otherwise, are the property of their respective owner.

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Progenics
Pharmaceuticals



The following is a Brief Summary; refer to the full Prescribing Information for complete information at www.AZEDRA.com

INDICATIONS AND USAGE

AZEDRA is indicated for the treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy.

DOSAGE AND ADMINISTRATION

Important Safety Information

AZEDRA is a radiopharmaceutical. Handle with appropriate safety measures to minimize radiation exposure. Use waterproof gloves and effective radiation shielding when handling AZEDRA. Radiopharmaceuticals, including AZEDRA, should be used by or under the control of physicians who are qualified by specific training and experience in the safe use and handling of radiopharmaceuticals, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radiopharmaceuticals.

Verify pregnancy status in females of reproductive potential prior to initiating AZEDRA.

Recommended Dosage

Administer thyroid blockade and other pre- and concomitant medications as recommended.

Dosimetric Dose

The recommended AZEDRA dosimetric dose administered as an intravenous injection is:

- Patients weighing greater than 50 kg: 185 to 222 MBq (5 or 6 mCi)
- Patients weighing 50 kg or less: 3.7 MBq/kg (0.1 mCi/kg)

Dosimetry and Biodistribution Assessment

Following the AZEDRA dosimetric dose:

- Acquire anterior/posterior whole body gamma camera images within 1 hour of the AZEDRA dosimetric dose and prior to patient voiding (Day 0; Scan 1).
- Acquire additional images on Day 1 or 2 following patient voiding (Scan 2).
- Acquire additional images between Days 2-5 following patient voiding (Scan 3).

For each individual patient, calculate the radiation dose estimates to normal organs and tissues per unit activity [D (organ)] of administered dose using data extracted from these 3 images. Calculate in accordance with the Medical Internal Radiation Dose (MIRD) schema or related methodology. Whenever possible, use patient-specific organ masses (e.g. estimated from imaging).

Therapeutic Dosage

The recommended AZEDRA therapeutic dose is based on body weight and reduced, if necessary, based on the dosimetry data. Administer a total of 2 therapeutic doses intravenously a minimum of 90 days apart.

Weight Based Dose per Therapeutic Cycle

- Patients weighing greater than 62.5 kg: 18,500 MBq (500 mCi)
- Patients weighing 62.5 kg or less: 296 MBq/kg (8 mCi/kg)

Determine if Dose Reduction Needed Based on Critical Organ Limits

- Calculate the estimated critical organ absorbed-dose by multiplying the dosimetry-derived radiation absorbed-dose per unit activity [D (organ)] by weight based therapeutic total activity (Aw).
- If resulting estimated critical organ absorbed-dose is less than threshold absorbed-dose (T) shown in Table 1, no dose adjustment is necessary.
- If resulting estimated critical organ absorbed-dose exceeds threshold absorbed-dose (T) shown in Table 1, calculate the reduced therapeutic total activity (i.e., the cumulative activity that would be administered in 2 therapeutic cycles) using the following equation:

Reduced Therapeutic Total Activity= Aw × [T ÷ {Aw × D (organ)}]

- Example: A 75 kg patient qualifies for a therapeutic total activity of 1000 mCi (Aw). For the kidneys, the dosimetry yields an estimated critical organ absorbed dose per unit activity of 0.027 Gy/mCi [D (kidney)]. Thus, the estimated critical organ absorbed-dose to the kidney is 27 Gy [Aw x D (organ)], which exceeds the threshold absorbed-dose for the kidneys (T) of 18 Gy (Table 1). Using the equation above the reduced therapeutic total activity to be administered to this patient is 666.7 mCi.

1000 mCi × [18 Gy ÷ {1000 mCi × 0.027 Gy/mCi}]

Table 1: Absorbed-dose Threshold Values for Radiation Toxicity in Critical Organs

Organ	~ 1%-rate: mortality or organ failure associated with disease	Time to death or organ failure	Threshold* absorbed-dose for ~1%-rate mortality or organ failure (Gy)
Red marrow	H-ARS mortality	1-2 months	12
Lungs	Pneumonitis mortality	1-7 months	16.5
Kidneys	Renal failure	>1 year	18
Liver	Hepatomegaly, ascites; possible organ failure	0.5-3 months	31
Small intestine	GI-ARS mortality	6-9 days	40

* Threshold of ~0.5 Gy for both heart and carotid artery, derived from experience with external-beam radiotherapy and associated with fractionated exposure, has also been proposed to support an ~1% mortality rate of cardiovascular and cerebrovascular deaths in >10-15 years. Great uncertainty is associated with the value ~ 0.5 Gy cited for vascular disease (ICRP publication 118, p.300, Table 4.5), consider benefits/risks to patients.

Thyroid Blockade and Other Pre- and Concomitant Medications

Thyroid Blockade

Administer inorganic iodine starting at least 24 hours before and continuing for 10 days after each AZEDRA dose.

Hydration

Instruct patients to increase fluid intake to at least two liters a day starting at least 1 day before and continuing for 1 week after each AZEDRA dose to minimize irradiation to the bladder.

Drugs that Reduce Catecholamine Uptake or Deplete Stores

Discontinue drugs that reduce catecholamine uptake or deplete catecholamine stores for at least 5 half-lives before administration of either the dosimetry dose or a therapeutic dose of AZEDRA. Do not administer these drugs until at least 7 days after each AZEDRA dose.

Antiemetic

Administer antiemetics 30 minutes prior to administering each AZEDRA dose.

Dose Modifications for Adverse Reactions

Recommended dose modifications of AZEDRA for adverse reactions are provided in Table 2 and the recommended dose or dose reduction for the second therapeutic dose of AZEDRA for myelosuppression are provided in Table 3.

Adverse Reaction	Dose Modification
Myelosuppression	Do not administer the first therapeutic dose for platelet counts less than 80,000/mcL or absolute neutrophil counts (ANC) less than 1,200/mcL. Do not administer the second therapeutic dose until platelets and neutrophils return to baseline or to the normal range. Reduce the second therapeutic dose for the following: <ul style="list-style-type: none">• platelet count less than 25,000/mcL, ANC less than 500/mcL, or life-threatening anemia for more than 7 days• febrile neutropenia• platelet count less than 50,000/mcL with active bleeding
Pneumonitis	<ul style="list-style-type: none">• Do not administer the second therapeutic dose if pneumonitis is diagnosed after the first therapeutic dose.

Table 3: Recommended Dose or Dose Reduction for Second Therapeutic Dose of AZEDRA for Myelosuppression

Patient Population	If first therapeutic dose was weight based,	If first therapeutic dose was reduced based on critical organ limits,
Patients weighing greater than 62.5 kg	Reduce the second therapeutic dose to 425 mCi	Reduce second therapeutic dose to 85% of the first dose
Patients weighing 62.5 kg or less	Reduce the second therapeutic dose to 7 mCi/kg	Reduce second therapeutic dose to 85% of the first dose

DOSAGE FORMS AND STRENGTHS

Injection: 555 MBq/mL (15 mCi/mL) as a clear, colorless to pale yellow solution in a single-dose vial.

WARNINGS AND PRECAUTIONS

Risk from Radiation Exposure

AZEDRA contributes to a patient's overall long-term radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk for cancer. These risks of radiation associated with the use of AZEDRA are greater in pediatric patients than in adults.

Minimize radiation exposure to patients, medical personnel, and household contacts during and after treatment with AZEDRA consistent with institutional good radiation safety practices and patient management procedures.

Myelosuppression

Severe and prolonged myelosuppression occurred during treatment with AZEDRA. Among the 88 patients who received a therapeutic dose of AZEDRA, 33% experienced Grade 4 thrombocytopenia, 16% experienced Grade 4 neutropenia, and 7% experienced Grade 4 anemia. Five percent of patients experienced febrile neutropenia. In Study IB12B following the first therapeutic dose, patients who experienced Grade 4 neutropenia reached neutrophil nadir at a median of 36 days (27 – 55 days) and

remained at nadir for a median of 12 days (8 – 22 days) until recovery to less than or equal to Grade 3. Following the second dose, patients who experienced Grade 4 neutropenia reached nadir at a median of 43 days (38 – 47 days) and remained at nadir for a median of 18.5 days (8 – 31 days) until recovery to less than or equal to Grade 3.

Monitor blood cell counts weekly for up to 12 weeks or until levels return to baseline or the normal range. Withhold and dose reduce AZEDRA as recommended based on severity of the cytopenia.

Secondary Myelodysplastic Syndrome, Leukemia and Other Malignancies

Myelodysplastic syndrome (MDS) or acute leukemias were reported in 6.8% of the 88 patients who received a therapeutic dose of AZEDRA. The time to development of MDS or acute leukemia ranged from 12 months to 7 years.

Two of the 88 patients developed a non-hematological malignancy. One patient developed colon cancer at 18 months and one patient developed lung adenocarcinoma at 27 months following the first therapeutic dose.

Hypothyroidism

Hypothyroidism was reported in 3.4% of the 88 patients who received a therapeutic dose of AZEDRA. The time to worsening of hypothyroidism was 4 months in one patient, and the time to development of hypothyroidism was less than one month in one patient and 18 months in one patient. Initiate thyroid-blocking medications starting at least 1 day before and continuing for 10 days after each AZEDRA dose to reduce the risk of hypothyroidism or thyroid neoplasia. Evaluate for clinical evidence of hypothyroidism and measure thyroid-stimulating hormone (TSH) levels prior to initiating AZEDRA and annually thereafter.

Elevations in Blood Pressure

Eleven percent of the 88 patients who received a therapeutic dose of AZEDRA experienced a worsening of pre-existing hypertension defined as an increase in systolic blood pressure to ≥160 mmHg with an increase of 20 mmHg or an increase in diastolic blood pressure to ≥ 100 mmHg with an increase of 10 mmHg. All changes in blood pressure occurred within the first 24 hours post infusion. Monitor blood pressure frequently during the first 24 hours after each therapeutic dose of AZEDRA.

Renal Toxicity

Of the 88 patients who received a therapeutic dose of AZEDRA, 7% developed renal failure or acute kidney injury and 22% demonstrated a clinically significant decrease in glomerular filtration rate (GFR) measured at 6 or 12 months. Monitor renal function during and after treatment with AZEDRA. Patients with baseline renal impairment may be at greater risk of toxicity; perform more frequent assessments of renal function in patients with mild or moderate impairment. AZEDRA has not been studied in patients with severe renal impairment (creatinine clearance <30 mL/min).

Pneumonitis

Fatal pneumonitis occurred 9 weeks after a single dose in one patient in the expanded access program for Study IB12B (n=11). Pneumonitis was not diagnosed among the 88 patients enrolled in Study IB12 or IB12B. Monitor patients for signs and symptoms of pneumonitis and treat appropriately.

Embryo-Fetal Toxicity

Based on its mechanism of action, AZEDRA can cause fetal harm. There are no available data on the use of AZEDRA in pregnant women. No animal studies using iobenguane I 131 have been conducted to evaluate its effect on female reproduction and embryo-fetal development; however, all radiopharmaceuticals, including AZEDRA, have the potential to cause fetal harm.

Verify pregnancy status in females of reproductive potential prior to initiating AZEDRA.

Advise females and males of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with AZEDRA and for 7 months after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 4 months after the final dose.

Risk of Infertility

Radiation exposure associated with AZEDRA may cause infertility in males and females. The recommended cumulative dose of 37 GBq of AZEDRA results in a radiation absorbed dose to the testes and ovaries within the range where temporary or permanent infertility can be expected following external beam radiotherapy.

ADVERSE REACTIONS

The following serious adverse reactions are described elsewhere in the labeling:

- Myelosuppression
- Secondary Myelodysplastic Syndrome, Leukemia and Other Malignancies
- Hypothyroidism
- Elevations in Blood Pressure
- Renal Toxicity
- Pneumonitis

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 data in Warnings and Precautions reflect exposure to AZEDRA in 88 patients with iobenguane-scan positive recurrent or unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma (PPGL) who received a therapeutic dose of AZEDRA in one of two clinical studies (IB12 or IB12B). The Warnings and Precautions also include data from 11 patients enrolled in an expanded access program for Study IB12B.

The safety data below was evaluated in two studies in patients with recurrent or unresectable, locally advanced or metastatic PPGL. Study

IB12 was an open-label, multi-center, single-arm dose-finding study in adult patients with malignant or recurrent PPGL. The study consisted of a 12-month efficacy phase with a 1 year follow-up. Twenty-one patients received a dosimetric dose (~5 mCi), followed by one therapeutic dose (~500 mCi) of AZEDRA. Study IB12B was an open-label, multi-center, single-arm study in 68 adult and pediatric patients age 12 years and older with recurrent or unresectable, locally advanced or metastatic PPGL.

Patients with evidence of liver dysfunction (aspartate aminotransferase or alanine aminotransferase ≥ 2.5 times the upper limit of normal or total bilirubin > 1.5 times the upper limit of normal), a history of liver disease (including hepatitis and chronic alcohol abuse), or severe renal impairment (creatinine clearance < 30 mL/min) were excluded. Patients who had received external beam radiation to > 25% of bone marrow, received whole body radiotherapy, or who had received any systemic radiotherapy resulting in myelosuppression within 3 months of study entry, were also excluded. The safety data described below are based on pooled safety data from studies IB12 and IB12B. A total of 88 patients received at least one therapeutic dose of AZEDRA and 50 patients received two therapeutic doses (one patient received treatment in both studies).

Adverse reactions from studies IB12 and IB12B are presented in Table 4. The most common severe (Grade 3-4) adverse reactions were lymphopenia (78%), neutropenia (59%), thrombocytopenia (50%), fatigue (26%), anemia (24%), increased international normalized ratio (18%), nausea (16%), dizziness (13%), hypertension (11%), and vomiting (10%). Twelve percent of patients discontinued treatment due to adverse reactions (thrombocytopenia, anemia, lymphopenia, nausea and vomiting, multiple hematologic adverse reactions).

Table 4: Adverse Reactions Occurring in ≥10% of Patients with PPGL Receiving Therapeutic Dose of AZEDRA in Studies IB12B and IB12

Adverse Reaction	All Grades ^a , (%)	Grades ^a 3 - 4, (%)
Hematologic ^b		
Lymphopenia	96	78
Anemia	93	24
Thrombocytopenia	91	50
Neutropenia	84	59
Gastrointestinal		
Nausea	78	16
Vomiting ^c	58	10
Dry mouth	48	2
Saladenitis ^d	39	1
Diarrhea	25	3
Abdominal pain ^e	23	6
Constipation	19	7
Oropharyngeal pain	14	0
Dyspepsia	10	0
General		
Fatigue ^f	71	26
Pyrexia	14	2
Injection site pain	10	0
Hyperhidrosis	10	0
Alopecia	10	0
Infections		
Upper respiratory tract infection ^g	16	2
Urinary tract infection	11	1
Investigations ^h		
International normalized ratio increased ^h	85	18
Increased blood alkaline phosphatase	53	5
Increased aspartate aminotransferase	50	2
Increased alanine aminotransferase	43	2
Metabolism and nutrition		
Decreased appetite	30	5
Dehydration	16	4
Decreased weight	16	1
Musculoskeletal and connective tissue disorders		
Back pain	17	2
Pain in extremity	15	0
Nervous system		
Dizziness ⁱ	34	13
Headache	32	6
Dysgeusia ^j	24	1
Respiratory, thoracic, and mediastinal disorders		
Cough	18	0
Dyspnea	18	7
Vascular		
Hypotension	24	4
Hypertension ^k	20	11
Tachycardia	10	3

^a NCI CTCAE version 3.0.

^b Based on laboratory data.

^c Includes vomiting and retching.

^d Includes sialadenitis, salivary gland pain, and salivary gland enlargement.

^e Includes abdominal pain, abdominal pain upper, and abdominal pain lower.

^f Includes fatigue, asthenia.

^g Includes upper respiratory tract infection, sinusitis, rhinorrhea, upper-airway cough syndrome, nasopharyngitis.

^h Only assessed in Study IB12B (N=68).

ⁱ Includes dizziness and dizziness postural.

^j Includes dysgeusia, hypogeusia and ageusia.

^k Includes blood pressure increased and hypertension.

The following clinically significant adverse reactions were observed in < 10% of patients treated with AZEDRA:

Cardiac: palpitations (9%), syncope and presyncope (8%)

Endocrine: decreased TSH (5%), hypothyroidism (3%)

Gastrointestinal: dysphagia (7%), abdominal distension (6%), gastroesophageal reflux disease (6%), stomatitis (3%)

General: insomnia (9%), chills (8%), chest pain (6%)

Infections: candida infection (6%)

Investigations: prolonged prothrombin time (9%)

Musculoskeletal and connective tissue: arthralgia (8%), neck pain (8%), pain in jaw (7%), muscle spasms (6%)

Renal and urinary disorders: proteinuria (9%), renal failure (7%),

Respiratory: epistaxis (9%), nasal congestion (7%), pulmonary embolism (3%)

Skin and subcutaneous tissue: dry skin (8%), rash (8%), petechiae (7%)

Vascular: orthostatic hypotension (9%).

DRUG INTERACTIONS

Drugs that Reduce Catecholamine Uptake or Deplete Stores

Based on the mechanism of action of iobenguane, drugs that reduce catecholamine uptake or that deplete catecholamine stores may interfere with iobenguane uptake into cells and therefore interfere with dosimetry calculations or the efficacy of AZEDRA. These drugs were not permitted in clinical trials that assessed the safety and efficacy of AZEDRA. Discontinue drugs that reduce catecholamine uptake or deplete catecholamine stores, such as those listed below, for at least 5 half-lives before administration of either the dosimetry dose or a therapeutic dose of AZEDRA. Do not administer these drugs until at least 7 days after each AZEDRA dose.

- CNS stimulants or amphetamines (e.g. cocaine, methylphenidate, dextroamphetamine)
- Norepinephrine and dopamine reuptake inhibitors (e.g. phenteramine)
- Norepinephrine and serotonin reuptake inhibitors (e.g. tramadol)
- Monoamine oxidase inhibitors (e.g. phenelzine and linezolid)
- Central monoamine depleting drugs (e.g. reserpine)
- Non-select beta adrenergic blocking drugs (e.g. labetalol)
- Alpha agonists or alpha/beta agonists (e.g. pseudoephedrine, phenylephrine, ephedrine, phenylpropanolamine, naphazoline)
- Tricyclic antidepressants or norepinephrine reuptake inhibitors (e.g. amitriptyline, bupropion, duloxetine, mirtazapine, venlafaxine)
- Botanicals that may inhibit reuptake of norepinephrine, serotonin or dopamine (e.g. ephedra, ma huang, St John's Wort, or yohimbine)

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Based on its mechanism of action, AZEDRA can cause fetal harm. There are no available data on AZEDRA use in pregnant women. No animal studies using iobenguane I 131 have been conducted to evaluate its effect on female reproduction and embryo-fetal development; however, all radiopharmaceuticals, including AZEDRA, have the potential to cause fetal harm. Advise pregnant women of the risk to a fetus.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Lactation

Risk Summary

There are no data on the presence of iobenguane I 131 in human milk or its effects on the breastfed infant or milk production. No lactation studies in animals were conducted. Because of the potential risk for serious adverse reactions in breastfed infants, advise women not to breastfeed during treatment with AZEDRA and for 80 days after the final dose.

Females and Males of Reproductive Potential

Pregnancy Testing

Verify pregnancy status in females of reproductive potential prior to initiating AZEDRA.

Contraception

AZEDRA can cause fetal harm when administered to a pregnant woman.

Females

Advise women of reproductive potential to use effective contraception during treatment with AZEDRA and for 7 months following the final dose of AZEDRA.

Males

Based on its mechanism of action, advise males with female partners of reproductive potential to use effective contraception during treatment with AZEDRA and for 4 months following the final dose of AZEDRA.

Infertility

The recommended cumulative dose of 37 GBq of AZEDRA results in a radiation absorbed dose to the testes and ovaries within the range where temporary or permanent infertility can be expected following external beam radiotherapy.

Pediatric Use

The safety and effectiveness of AZEDRA have been established in patients 12 years and older with unresectable and iobenguane scan positive, locally advanced or metastatic, pheochromocytoma and paraganglioma (PPGL) which require systemic anticancer therapy. Use of AZEDRA for this indication is supported by evidence from an adequate and well-controlled study in adults and pediatric patients 12 years and older.

The risks of radiation associated with AZEDRA is greater in pediatric patients than that in adult patients due to greater absorbed radiation doses and longer life expectancy. Ensure the therapeutic benefit of AZEDRA outweighs these greater risks prior to administration in pediatric patients.

The safety and effectiveness of AZEDRA have not been established in pediatric patients younger than 12 years old with unresectable and iobenguane scan positive, locally advanced or metastatic PPGL which require systemic anticancer therapy.

Geriatric Use

Of the patients enrolled in all clinical studies of AZEDRA, 17% were 65 years or older and 1% were 75 years or older. Clinical studies of AZEDRA did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

Renal Impairment

The radiation dose to patients with renal impairment may be increased due to the delayed elimination of the drug. Adjust the therapeutic dose based on radiation exposure estimates from the dosimetry assessment. The safety of AZEDRA in patients with severe renal impairment (CLcr < 30 mL/min) or end-stage renal disease has not been studied.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity studies with iobenguane I 131 have not been conducted; however, radiation is a carcinogen and a mutagen. No animal studies were conducted to determine the effects of iobenguane I 131 on fertility.

PATIENT COUNSELING INFORMATION

Hydration

Advise patients to drink at least 2 liters of liquid a day before and for one week following each dose of AZEDRA to minimize irradiation of the bladder.

Radiation Risks

Advise patients to minimize radiation exposure to household contacts consistent with institutional good radiation safety practices and patient management procedures.

Myelosuppression

Advise patients to contact their health care provider for any signs or symptoms of neutropenia, thrombocytopenia, or anemia.

Secondary Myelodysplastic Syndrome, Leukemia and Other Malignancies

Advise patients of the potential for secondary cancers, including myelodysplastic syndrome, acute leukemia, and other malignancies.

Hypothyroidism

Advise patients to take thyroid-blocking agents as prescribed. Advise patients of the need for life-long monitoring for hypothyroidism.

Elevations in Blood Pressure

Advise patients to contact their health care provider for signs or symptoms that may occur following tumor-hormone catecholamines release and possible risk of increased blood pressure during or 24 hours following each therapeutic AZEDRA dose.

Pneumonitis

Advise patients to contact their health care provider for signs or symptoms of pneumonitis.

Drug Interactions

Advise patients that some medicines interact with AZEDRA and to contact their health care provider before starting any over the counter medicines or herbal or dietary supplements

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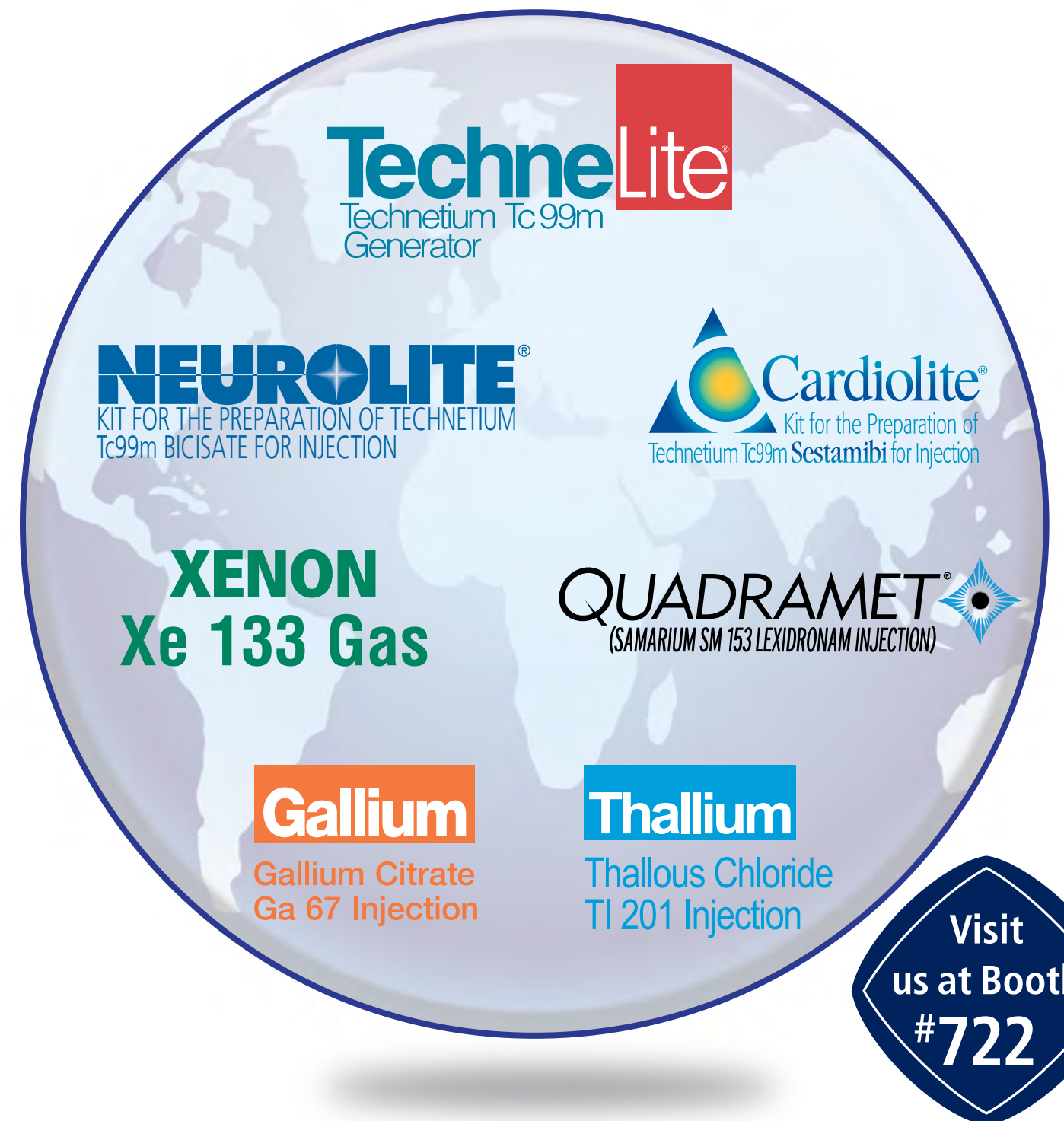
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