# PREVIEWMAGAZINE

ISSUE TWO ▪ WWW.SNMMI.ORG/VIRTUALPREVIEW

July 11-14

## SNMMI2020 ANNUAL MEETING VIRTUAL Edition

*Diagnosis to Therapy* The Future of Image-Guided Patient Management

## *In This Issue*


- **Plenary Speaker Announcements**
  See who's leading this year's plenary sessions!
- **Key Topics. Top Speakers.**
  Explore the meeting's carefully crafted educational program.

# Expected results. **Delivered.**

## Are you getting the most out of your Rb-82 Generator?

The RUBY-FILL® Rubidium 82 Generator is clinically proven to deliver industry-leading efficiency with reliable consistency and dosing flexibility[1-3]


## RUBY-FILL® has been proven to

**Consistently deliver expected yield with nearly 100% accuracy**

- In a recent study comparing currently available generators, RUBY-FILL® showed industry-leading efficiency[3]

**Deliver highly accurate patient doses**

- Over the life of the generator, the deviation of delivered dose vs. requested dose approached 0%[3]

**Provide clinical flexibility**

- RUBY-FILL® provides a long shelf life and flexible, patient-specific dosing[1]

Seem unbelievable?
Visit **Jubilant Radiopharma** at the SNMMI Virtual Meeting Online July 11- 13 to see for yourself

RUBY FILL®
RUBIDIUM Rb82 GENERATOR

**Indication for Use:** RUBY-FILL is a closed system used to produce rubidium (Rb-82) chloride injection for intravenous use. Rubidium (Rb-82) chloride injection is a radioactive diagnostic agent indicated for Positron Emission Tomography (PET) imaging of the myocardium under rest or pharmacologic stress conditions to evaluate regional myocardial perfusion in adult patients with suspected or existing coronary artery disease.

**New Important Safety Information April 2019**
Please note changes in Boxed Warning, Dosage and Administration, Directions for Eluting Rubidium Rb 82 Chloride Injection (2.5), Contraindications (4), Warnings and Precautions, High Level Radiation Exposure with Use of Incorrect Eluent (5.1).

**WARNING: HIGH LEVEL RADIATION EXPOSURE WITH USE OF INCORRECT ELUENT AND FAILURE TO FOLLOW QUALITY CONTROL TESTING PROCEDURE**

*Please see full prescribing information for complete boxed warning*

**High Level Radiation Exposure with Use of Incorrect Eluent**
Using the incorrect eluent can cause high Strontium (Sr 82) and (Sr 85) breakthrough levels (5.1)

- Use only additive-free 0.9% Sodium Chloride Injection USP to elute the generator (2.5)
- Immediately stop the patient infusion and discontinue the use of the affected RUBY-FILL generator if the incorrect solution is used to elute the generator (4)
- Evaluate the patient's radiation absorbed dose and monitor for the effects of radiation to critical organs such as bone marrow (2.9)

**Excess Radiation Exposure with Failure to Follow Quality Control Testing Procedure**
Excess radiation exposure occurs when the levels of Sr 82 or Sr 85 in the rubidium Rb 82 chloride injection exceed specified limits (5.2)

- Strictly adhere to the generator quality control testing procedure (2.6)
- Stop use of a generator at any of its Expiration Limits (2.7)

The risk information provided here is not comprehensive. Please visit RUBY-FILL.com for full Prescribing Information including BOXED WARNING.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/Safety/MedWatch or call 1-800-FDA-1088.

**References: 1.** RUBY-FILL [package insert]. Kirkland, Quebec, Canada: Jubilant DraxImage Inc; April 2019. **2.** Renaud JM, Wiles M, Garrard L, Beanlands RSB, deKemp RA. New rubidium-82 generator efficiency improves over time. *J Nucl Med.* 2018;59(suppl 1):1045. **3.** Lewin HC, Millard A. Dose accuracy of 82Rb generator systems. Paper presented at: SNMMI Mid-Winter Meeting; January 17–19, 2019; Palm Springs, CA.

JUBILANT RADIOPHARMA

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# A Re-Imagined Experience: Virtually Connecting You with Your Colleagues from Around the World!

The **SNMMI 2020 Annual Meeting - Virtual Edition**—Saturday, July 11 through Tuesday, July 14—gives you the unique opportunity to attend live continuing education sessions, review hundreds of scientific abstracts, connect with suppliers in the exhibit hall, and network with other attendees—**all in an exciting, interactive virtual environment**.

Best of all, the easy-to-use platform will mimic the dynamics of an in-person event, making it easy to navigate around and take full advantage of all the features the meeting has to offer. All you will need is an internet connection!

**The SNMMI Annual Meeting - Virtual Edition connects you with:**

### An Immersive Virtual Learning Experience

More than 25 one-hour sessions will be available over 3.5 days, featuring live chat functionality during live broadcasts of the presentations. Miss a session? Each session will be available for on-demand viewing following its live broadcast.

### Leading Research in the New Science Pavilion

View abstract presentations and posters of the profession's latest research, including recorded oral presentations from the authors. You will also be able to ask the authors questions by emailing them while visiting their poster/abstract.

### Industry Suppliers in an Interactive Exhibit Hall

Visit customized virtual booths from top suppliers and learn more about their products/services through videos and downloadable presentations. Plus, connect through one-on-one meetings with exhibit personnel while visiting their booth.

### Innovative Networking Opportunities

Interact with fellow attendees through one-on-one and group chat, and during great networking events, including Molecular Hub Meet-Ups, Saturday night Movie Viewing Party, the Presidents' Town Hall and Reception, and more.

### No Registration Fee for SNMMI Members

Although registration is required, the Annual Meeting - Virtual Edition is free for SNMMI members. Non-members may either join SNMMI to attend at no cost or pay a modest fee. ***Please note: registration closes at 11:59 pm ET on Thursday, July 9.***

**WWW.SNMMI.ORG/VIRTUALPREVIEW**

## THANK YOU TO OUR TITLE SPONSOR

We would like to recognize our title sponsor, Advanced Accelerator Applications, a Novartis Company, for their generous support of the SNMMI 2020 Annual Meeting - Virtual Edition.

Advanced Accelerator Applications
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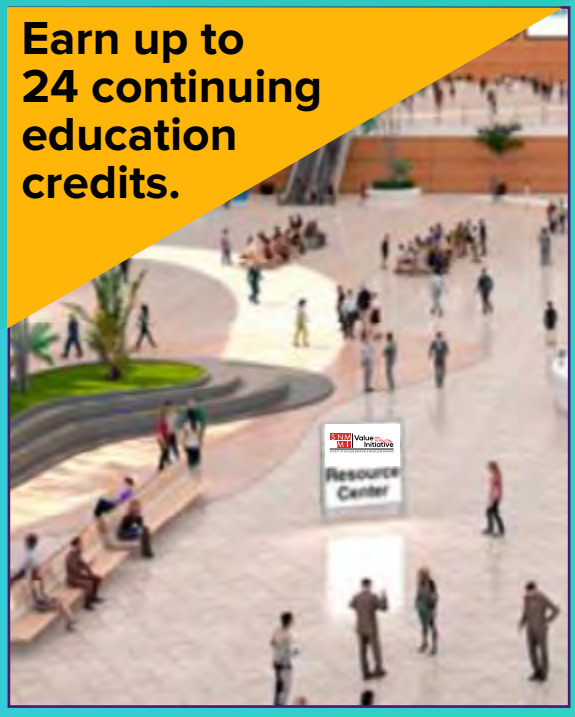
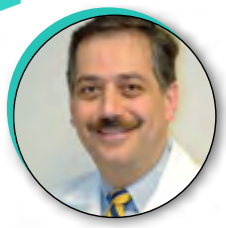


# PLENARY SESSIONS

The **SNMMI 2020 Annual Meeting** – Virtual Edition will continue to feature the anticipated Plenary Sessions. These sessions feature addresses by key luminaries, highlight significant awards and accomplishments, the installation of the new SNMMI president, a synopsis of research during the Annual Meeting, announcement of the Image of the Year, and more!



**Sunday, July 12 ▸ 10:00–11:00 am**
**"SNMMI President's Address"**

**Monday, July 13 ▸ 10:00–11:00 am**
**"SNMMI Year in Review"**
Vasken Dilsizian, MD

**Tuesday, July 14 ▸ 10:00–11:00 am**
**SNMMI-TS Year in Review**
Mark Crosthwaite, CNMT, FSNMMI-TS

**Sunday, July 12 ▸ 10:00–11:00 am**
**Henry N. Wagner, Jr., MD, Lectureship**
**"Molecular Imaging in Cardiovascular Medicine: Setting Tiny Targets for Greater Goals"**
Jagat Narula, MD, PhD, MACC

**Tuesday, July 14 ▸ 6:15–8:00 pm**
**Henry N. Wagner, Jr., MD, Highlights Lecture: Cardiology**
Mehran Sadeghi, MD

**Monday, July 13 ▸ 10:00–11:00 am**
**Benedict Cassen, MD, Lectureship**
**"Imaging in 2020 and Beyond: Expect the Unexpected"**
Peter Conti, MD, PhD

**Tuesday, July 14 ▸ 6:15–8:00 pm**
**Henry N. Wagner, Jr., MD, Highlights Lecture: General Nuclear Medicine**
Heather Jacene, MD

**Tuesday, July 14 ▸ 10:00–11:00 am**
**SNMMI-TS Plenary Session**
**"Radionuclide Therapy during COVID-19"**
Lisa Bodei, MD, PhD

**Tuesday, July 14 ▸ 6:15–8:00 pm**
**Henry N. Wagner, Jr., MD, Highlights Lecture: Neuroscience**
Julie Price, PhD

**www.snmmi.org/AMPlenary**

**Tuesday, July 14 ▸ 6:15–8:00 pm**
**Henry N. Wagner, Jr., MD, Highlights Lecture: Oncology**
Andrew Scott, MD, FRACP, DDU, FAICD, FAHMS, FAANMS

# SCHEDULE AT A GLANCE VIRTUAL EDITION

## SATURDAY JULY 11, 2020

**1:30–2:30 pm**
Molecular Hub – Virtual Meeting Overview

**2:30–3:30 pm**
Opening/Welcome

**3:30–4:30 pm**
Non-Invasive Evaluation of CAD in 2020

**4:30–5:00 pm**
Visit the Exhibit Hall

**5:00–6:00 pm**
YIA #1 - Cardiovascular

**6:00–6:15 pm**
Break
Visit the Exhibit Hall
Visit the Science Pavilion

**6:15–7:15 pm**
YIA #2

**7:15–8:15 pm**
SNMMI-TS President's Town Hall/Reception

**8:15–10:15 pm**
Movie Night

## SUNDAY JULY 12, 2020

**9:00–10:00 am**
Molecular Hub – Council & Center Leadership

**10:00–11:00 am**
SNMMI President's Address/ Wagner Lecture

**11:00–11:15 am**
Break
Visit the Exhibit Hall
Visit the Science Pavilion

**11:15 am–12:15 pm**
Complementary Roles of Nuclear Medicine and Radiologic Imaging in the Evaluation of Musculoskeletal Diseases

**12:15–12:30 pm**
Break
Visit the Exhibit Hall
Visit the Science Pavilion

**12:30–1:30 pm**
Lymphoscintigraphy: Review of Basics, Use with SPECT/CT, and Viewpoint of a Surgeon

**1:30–2:30 pm**
Lunch Break –
Visit the Exhibit Hall –
Satellite Symposium
(two on each day)

**2:30–3:30 pm**
SPECT/CT Applications in Pediatrics

**3:30–4:30 pm**
Fundamentals of Brain SPECT/PET Scan Interpretation in Dementia

**4:30–5:00 pm**
Visit the Exhibit Hall

**5:00–6:00 pm**
YIA #3

**6:00–6:15 pm**
Break
Visit the Exhibit Hall
Visit the Science Pavilion

**6:15–7:15 pm**
BSS Session #1

**7:15–8:15 pm**
YIA #4 – Brain Imaging

**8:15 – 9:15 pm**
Drink & Think

## MONDAY JULY 13, 2020

**9:00–10:00 am**
Special Session – Nuclear Medicine in the Time of COVID-19

**10:00–11:00 am**
SNMMI Business Meeting/ Cassen Lecture

**11:00–11:15 am**
Break
Visit the Exhibit Hall
Visit the Science Pavilion

**11:15 am–12:15 pm**
Theranostics - How to Do Radiation Safety Right?

**12:15–12:30 pm**
Break
Visit the Exhibit Hall
Visit the Science Pavilion

**12:30–1:30 pm**
Best Practices to Support the Quality Control of PET Drugs

**1:30–2:30 pm**
Lunch Break –
Visit the Exhibit Hall –
Satellite Symposium
(two on each day)

**2:30–3:30 pm**
Current Perspective on Total Body PET and Applications

**3:30–4:30 pm**
Pearls and Pitfalls in PET: DOTATATE, Amyloid, Fluciclovine, PSMA

**4:30–5:00 pm**
Visit the Exhibit Hall

**5:00–6:00 pm**
YIA #5

**6:00–6:15 pm**
Break
Visit the Exhibit Hall
Visit the Science Pavilion

**6:15–7:15 pm**
BSS Session #2

**7:15–8:15 pm**
SNMMI President's Town Hall/ Reception

**8:15–9:15 pm**
Drink & Think

## TUESDAY JULY 14, 2020

**9:00–10:00 am**
Molecular Hub – Early Career Professionals

**10:00–11:00 am**
SNMMI-TS Plenary Session

**11:00–11:15 am**
Break
Visit the Exhibit Hall
Visit the Science Pavilion

**11:15 am–12:15 pm**
Practical Aspects and Concerns Associated with USP 825 Implementation

**12:15–12:30 pm**
Break
Visit the Exhibit Hall
Visit the Science Pavilion

**12:30–1:30 pm**
New Imaging Boot Camp: FES, $^{18}$F-DOPA, New Net Imaging Agents, FAPI

**1:30–2:30 pm**
Lunch Break –
Visit the Exhibit Hall –
Satellite Symposium
(two on each day)

**2:30–3:30 pm**
On the Horizon: Developing Techniques, New Isotopes and Production Chemistry

**3:30–4:30 pm**
Prostate Cancer Theranostics—Applications of Molecular Targeted Radiotherapy

**4:30–5:00 pm**
Visit the Exhibit Hall

**5:00–6:00 pm**
YIA #6

**6:00–6:15 pm**
Break
Visit the Exhibit Hall
Visit the Science Pavilion

**6:15–8:00 pm**
Highlights Lecture

**8:00–9:00 pm**
Knowledge Bowl

**Networking Event**

**CE Session**

**Scientific Session**

**Break**
**Visit the Exhibit Hall**
**Visit the Science Pavilion**

# CE SESSIONS

**The SNMMI 2020 Annual Meeting—Virtual Edition features state-of-the-art, interactive CE Sessions over 3.5 days. These sessions will be one-hour in length and will include live chat functionality to converse with speakers during their presentations.**

## ▸ CE01: Non-Invasive Evaluation of CAD in 2020

**Saturday, July 11 ▸ 3:30–4:30 pm**

*Organized by the Cardiovascular Council*

1. Optimizing SPECT MPI for the COVID19 Era — *Randall Thompson, MD*
2. PET is the Future of Nuclear Cardiology — *Marcelo Di Carli, MD*
3. Changing Guidelines and their Impact on Nuclear Cardiology — *Rory Hachamovitch, MD*
4. Competing Approaches to CAD Evaluation - CT-FFR, Stress CMR and Beyond — *Mouaz Husayn Al-Mallah, MD*

## ▸ CE02: Complementary Roles of Nuclear Medicine and Radiologic Imaging in the Evaluation of Musculoskeletal Diseases

**Sunday, July 12 ▸ 11:15 am–12:15 pm**

*Organized by the General Clinical Nuclear Medicine Council*

1. Optimizing SPECT MPI for the COVID19 — Era *Meera Raghavan, MD*

## ▸ CE03: Lymphoscintigraphy: Review of Basics, Use with SPECT/CT, and Viewpoint of a Surgeon

**Sunday, July 12 ▸ 12:30–1:30 pm**

*Organized by the Correlative Imaging Council*

1. A Review of the Basics of Lymphoscintigraphy — *Andrew Kozlov, MD*
2. Case-Based: How SPECT/CT Contributes to Sentinel Node Detection— *Lizette Louw, MD*
3. Viewpoint from a Surgeon: How Nuclear Medicine is Utilized for Sentinel Node Detection — *Steven D Jones, MD, MPH*

## ▸ CE04: SPECT/CT Applications in Pediatrics

**Sunday, July 12 ▸ 2:30–3:30 pm**

*Organized by the Pediatric Imaging Council*

1. Endocrine — *Adina Alazraki, MD*
2. Pulmonary — *J. Christopher Davis, MD*
3. Neuroblastoma: MIBG SPECT/CT — *Susan E. Sharp, MD*

## ▸ CE05: Fundamentals of Brain SPECT/PET Scan Interpretation in Dementia

**Sunday, July 12 ▸ 3:30–4:30 pm**

*Organized by the Brain Imaging Council*

1. How to Read and Interpret a Perfusion SPECT/FDG PET Scan— *Jonathan McConathy, MD, PhD*
2. How to Read and Interpret an Amyloid and Tau PET Scan— *Alexander E. Drzezga, MD*

## ▸ Special Session – Nuclear Medicine in the Time of Covid-19

**Monday, July 13 ▸ 9:00–10:00 am**

*Organized by the SNMMI COVID-19 Taskforce*

1. The COVID-19 Pandemic: A Resident's Perspective — *Anthony Hafez, DO*
2. The COVID-19 Pandemic: A Technologist's Viewpoint — *Maria C. DaCosta, CNMT*
3. The COVID-19 Pandemic: A Faculty's Perspective — *Munir Ghesani, MD, FACNM, FACR*

# CE SESSIONS

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## CE06: Theranostics — How to do Radiation Safety Right?

**Monday, July 13 ▸ 11:15 am–12:15 pm**

*Organized by the Quality and Evidence Committee*

1. Patient Release after 131-I Therapy (NaI and MIBG) — *Frederick D. Grant, MD*
2. Safe use of 223-Ra, 90-Y and 177-Lu Labeled Agents — *Michael Sheetz, MS, CHP, DABMP*
3. Promoting Radiation Safety through SAFRON — *Debbie Gilley*

## CE07: Best Practices to Support the Quality Control of PET Drugs

**Monday, July 13 ▸ 12:30–1:30 pm**

*Organized by the Radiopharmaceutical Sciences Council*

1. General Regulations and Requirements— *Sally Schwarz, MS, RPh, BCNP, FAPhA*
2. Best Practices of QC for PET Drugs — *Denise Jeffers, RPh, ANP*
3. Field Notes — Common Issues and Pitfalls in QC — *Amy Vavere, PhD*

## CE08: Current Perspective on Total Body PET and Applications

**Monday, July 13 ▸ 2:30–3:30 pm**

*Organized by the Physics, Instrumentation, and Data Sciences Council*

1. Design Considerations for a Whole-Body PET Imager: Is there an optimal axial length? — *Joel S. Karp, PhD*
2. One year in the use of Explorer: What have we learned? — *Ramsey Badawi, PhD*
3. Clinical and Research Opportunities of Total Body PET at University of Pennsylvania — *Austin R. Pantel, MD*
4. Dynamic Whole-Body PET and Parametric Imaging — *Nicolas A. Karakatsanis, PhD*

## CE09: Pearls and Pitfalls in PET: DOTATATE, Amyloid, Fluciclovine, PSMA

**Monday, July 13 ▸ 3:30–4:30 pm**

*Organized by the PET Center of Excellence*

1. Pearls and Pitfalls: $^{68}$Ga DOTATATE — *Kalpna Prasad, MD*
2. Pearls and Pitfalls: Amyloid PET — *Twyla Bartel, DO*
3. Pearls and Pitfalls: Fluciclovine and PSMA — *Medhat Osman MD*

## TS01: Practical Aspects and Concerns Associated with UPS 825 Implementation

**Tuesday, July 14 ▸ 11:15 am–12:15 pm**

*Organized by the SNMMI Technologist Section*

1. History and Development of USP 825 — *James Ponto, MS, RPh, BCNP*
2. USP 825 Standard: Implementation into Current Practices — *Wendy Galbraith*

## CE10: New Imaging Boot Camp: FES, $^{18}$F-DOPA, New NET Imaging Agents, FAPI

**Tuesday, July 14 ▸ 12:30–1:30 pm**

*Organized by the Clinical Trials Network*

1. $^{18}$Fluoroestradiol (FES) — *Farrokh Dehdashti, MD*
2. $^{18}$F-DOPA - Oncology, Movement Disorder, and CHI — *Jonathan McConathy, MD, PhD*
3. New NET Imaging Agents ($^{64}$Cu-dotatate, $^{68}$Ga-dotatoc) — *Andreas Kjaer, MD, PhD*
4. FAPI for Imaging and Therapy — *Ken Herrmann, MD*

# CE SESSIONS

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## ▸ CE11: On the Horizon - Developing Techniques, New Isotopes and Production Chemistry

**Tuesday, July 14 ▸ 2:30–3:30 pm**

*Organized by the Center for Molecular Imaging Innovation and Translation (CMIIT)*

1. Radiolabeling Comparison of Accelerator Versus Generator Produced Ac-225
   *Vanessa A. Sanders, PhD*
2. 47Sc- cDTPA-TOC from Harvested Calcium
   *E. Paige Abel*
3. A Dual Generator Concept to Yield 226Th - An Isotope of Interest for Targeted Alpha Therapy
   *Mitchell Friend, MD*
4. Production of Theragnostic Radio-Scandium
   *Suzanne E. Lapi, PhD*

## ▸ CE12: Prostate Cancer Theranostics - Applications of Molecular Targeted Radiotherapy

**Tuesday, July 14 ▸ 3:30–4:30 pm**

*Organized by the Therapy Center of Excellence*

1. Prostate Cancer Osseous Radiotherapy
   *Chadwick L. Wright, MD, PhD*
2. Alpha Emitting PSMA Radiotheranostics
   *Hossein Jadvar, MD, PhD, FACNM, FSNMMI*
3. Gastrin-Releasing Peptide Receptor Radiotheranostics
   *Andrei Iagaru, MD*

# SATELLITE SYMPOSIUMS

SNMMI is pleased to once again Industry Satellite Symposiums during the Annual Meeting. These one-hour sessions provide a forum for our industry partners to directly address the nuclear medicine and molecular imaging community. SNMMI does not endorse any products or services referenced in these symposiums.

### The Role of LUTATHERA® (lutetium Lu 177 dotatate) in Patients With Progressive GEP-NETs

**Sunday, July 12 ▸ 1:30-2:30 pm ET**

*Sponsored by Advanced Accelerator Applications*

*Dr. Eric Liu, MD, FACS (Rocky Mountain Cancer Centers, Denver, Colorado)*

### Estrogen Receptor PET/CT Imaging with a Novel Biomarker: Underlying Biology, Biochemistry and Clinical Application

**Sunday, July 12 ▸ 1:30-2:30 pm ET**

*Sponsored by Siemens*

*David Mankoff, MD, PhD, Gerd Muehllehner Professor of Radiology, Perelman School of Medicine, University of Pennsylvania, Philadelphia*

### PSMA Imaging: Current Status and Prospects

**Monday, July 13 ▸ 1:30-2:30 pm ET**

*Sponsored by Telix Pharmaceuticals*

*Alton O. Sartor MD, Piltz Professor of Cancer Research, Departments of Medicine Hematology/Medical Oncology Tulane Medical Center*

*Jeffery Karnes, MD, Mayo Clinic Rochester, Minn.*

*Jeremie Calais, MD, MSc, Assistant Professor at the Ahmanson Translational Imaging Division of the Dept. of Molecular & Medical Pharmacology*

### SATELLITE SYMPOSIUM

**Monday, July 13 ▸ 1:30-2:30 pm ET**

*Sponsored by Siemens*

### Critical Considerations in Managing Patients With Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)

**Tuesday, July 14 ▸ 1:30-2:30 pm ET**

*Sponsored by Advanced Accelerator Applications*

*Dr Munir Ghesani, MD [Mount Sinai Hospital, New York]; Dr Erin E. Grady, MD [Emory University Hospital, Atlanta, Georgia]*

### Development & Application of Novel PET Tracer for AMPA Receptors

**Tuesday, July 14 ▸ 1:30-2:30 pm ET**

*Sponsored by Eisai*

*Takuya Takahashi, MD, PhD; Professor, Department of Physiology; Yokohama City University Graduate School of Medicine, Japan*

# VIRTUAL EXHIBIT HALL

**Visit customized virtual booths from top suppliers and learn more about their products/services through videos and downloadable presentations. Plus, connect through one-on-one meetings with exhibit personnel while visiting their booth.**

## EXHIBITING COMPANIES INCLUDE:

ABX-CRO advanced pharmaceutical services

ACIC - PBL

Actinium Pharmaceuticals

Advanced Accelerator Applications, a Novartis Company

Alzheimer's Association

American Board of Nuclear Medicine (ABNM)

American College of Nuclear Medicine (ACNM)

American College of Radiology (ACR)

AnazaoHealth Corporation

Applied Nanotech, Inc.

ARRT, The American Registry of Radiologic Technologists

Asia Oceania Federation of Nuclear Medicine and Biology (AOFNMB)

Astellas Pharma US

Bayer Oncology

Bayer - Radiology

Biodex Medical Systems, Inc.

Blue Earth Diagnostics,Inc.

Bracco Diagnostics

Bruker BioSpin

Canon Medical Systems USA, Inc.

Capintec, Inc. (part of Mirion Technologies)

Cardinal Health

Curium

Cyclomedical International, Inc.

Digirad Corporation

DOTmed HealthCare Business News

$ec^2$ Software Solutions

The Education and Research Foundation for Nuclear Medicine and Molecular Imaging (ERF)

European Association of Nuclear Medicine (EANM)

GE Healthcare

Hermes Medical Solutions, Inc.

Huayi Isotopes Company

Intersocietal Accreditation Commission (IAC)

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Jubilant Radiopharma

*As of June 2, 2020*

# VIRTUAL EXHIBIT HALL

**Visit customized virtual booths from top suppliers and learn more about their products/services through videos and downloadable presentations. Plus, connect through one-on-one meetings with exhibit personnel while visiting their booth.**

## EXHIBITING COMPANIES INCLUDE:

Lantheus Medical Imaging, Inc.

Life Molecular Imaging

Lilly

Lucerno Dynamics, LLC

MarShield Radiation Protection Products

MedImage, Inc.

MiE America

MILabs

MIM Software Inc.

MOLECUBES NV

MR SOLUTIONS

Northstar Medical Radioisotopes, LLC

Nuclear Medicine Technology Certification Board (NMTCB)

NUCMEDCOR

PETNET Solutions

Philips

PMB ALCEN

PMOD Technologies LLC

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Progenics Pharmaceuticals - Medical Affairs

RadioMedix

RI-TE Radiation Imaging Technologies, Lda

Scoperta Life Sciences

Siemens Healthineers

Sirona Complete Care

SHINE Medical Technologies, LLC

South West Exposures

Spectrum Dynamics Medical, Inc.

Telix Pharmaceuticals

Tema Sinergie

Triskem International

TTG Imaging Solutions

United Imaging

Universal Medical Resources, Inc.

Versant Medical Physics and Radiation Safety

World Molecular Imaging Society (WMIS)

*As of June 2, 2020*

# NETWORKING EVENTS

## Movie Viewing Party

*Organized by the Women in Nuclear Medicine Committee (WINM)*
*Sponsored by Bracco Diagnostics*
**Saturday, July 11 ▸ beginning at 7:15 pm ET**

Join the WINM for a movie viewing party of the popular film: ***"Radioactive"*** Plus, be on the lookout for a special announcement!

## Molecular Hub

Take a break from the CE sessions and join your colleagues at the Virtual Molecular Hub! Each day will feature a new topic and leaders within the field.

We invite you to begin your SNMMI Virtual Meeting experience on **Saturday, July 11 at 1:30 pm**. Umar Mahmood, MD, PhD, SNMMI Scientific Program Committee Chair will be providing an overview of the **Virtual Meeting platform**. Learn how to navigate the meeting, connect with friends and colleagues and visit the exhibit hall.

On **Sunday, July 12 at 9:00 am** join the **Council and Center Leadership** as they provide brief overviews of their activities and important information on how to get involved and connect with other individuals in your area of expertise.

Finally, on **Tuesday, July 14 at 9:00 am**, residents and early career professionals are invited to the join the **Early Career Professionals Committee**. Learn from the ECP leaders what resources, how to get involved and provide your feedback on the needs of the early career professional community.

## Knowledge Bowl

**Tuesday, July 14 ▸ 8:00-9:00 pm ET**

The SNMMI Early Career Professionals Committee (EPC) is excited to sponsor the Virtual Knowledge Bowl again this year! This event provides an opportunity for residents and early career professionals to network with each other in a competition of the mind! Attendees will be shown difficult general nuclear medicine and PET tracer cases, examine basic science questions and interpret important correlative imaging findings. All of this in a fun, interactive virtual platform.

# NETWORKING EVENTS

## Drink and Think

Join your colleagues and friends for an informal virtual networking event. Drink and Think is where a virtual happy hour meets an exchange of scientific knowledge and discussion. The Virtual Meeting will feature two day of opportunities to participate in Drink and Think meet-ups which will include topics hosted by SNMMI Councils and Centers. We encourage you to grab a late evening snack, a drink, and be ready to discuss some of the most exciting topics in the field. A list of the schedule topics are included below:

### Sunday, July 12 ▸ 8:15-9:15 pm ET

- Phased Re-opening Plans for Pediatric Nuclear Radiology Departments – *Sponsored by the Pediatric Imaging Council*
- New PET Radiopharmaceuticals: Practical Tips? – *Sponsored by the PET Center of Excellence*
- Artificial Intelligence in Nuclear Medicine – *Sponsored by the Physics, Instrumentation and Data Sciences Council*
- Prostate Imaging with PSMA PET and How it Plays into Other Imaging Modalities – *Sponsored by the Correlative Imaging Council*
- Expert Eyes on Details - Deep Cerebellar Nuclei in Neurodegenerative Imaging by Kuhl-Lassen Award Winner, Dr Nicolas Bohnen — *Sponsored by the Brain Imaging Council*
- How Toxic Environments Affect Productivity — *Sponsored by the CMIIT*

### Monday, June 13 ▸ 8:15-9:15 pm ET

- Total Body PET – *Sponsored by the Physics, Instrumentation and Data Sciences Council*
- Targeted Radionuclide Therapy for Non- thyroid Pediatric Malignancies: What's Here and What's on the Horizon? – *Sponsored by the Pediatric Imaging Council*
- Nuclear Medicine and COVID-19 – *Sponsored by the General Clinical Nuclear Medicine Council*
- 21CFR2Beers...Regulatory Considerations for the Radiopharmaceutical Sciences in 2020 – *Sponsored by the Radiopharmaceutical Sciences Council*
- Nuclear Medicine Practice Optimization – Opportunity for Physician Extenders – *Sponsored by the Advanced Associate Council*
- Resident Training and Recruitment in the Time of Covid – *Sponsored by the Academic Council*
- What are You Most Excited About with the Future of Nuclear Medicine Therapies? – *Sponsored by the Therapy Center of Excellence*

# NETWORKING EVENTS

## SNMMI-TS President's Reception

**Saturday, July 11, 2020 ▸ 7:15 pm ET**

*Honoring: Mark Crosthwaite, CNMT, FSNMMI-TS — SNMMI-TS President*

Join your colleagues on Saturday, July 11 at 7:15 pm ET, as SNMMI honors outgoing SNMMI-TS President Mark Crosthwaite, CNMT, FSNMMI-TS. This informal one-hour virtual town hall and reception will feature brief remarks from Mr. Crosthwaite, as well as a question and answer period for you to interact directly with the outgoing president. Plus, don't miss The Thallium Stallions, who will debut their new "COVID-19" song at the start of the reception – sponsored by Sirona Complete Care.



## SNMMI President's Reception

**Monday, July 13, 2020 ▸ 7:15 pm ET**

*Honoring: Vasken Dilsizian, MD — SNMMI President*

Join your colleagues on Monday, July 13 at 7:15 pm ET, as SNMMI honors outgoing SNMMI President Vasken Dilsizian, MD. This informal one-hour virtual town hall and reception will feature live music and brief remarks from Dr. Dilsizian, as well as a question and answer period for you to interact directly with the outgoing president.


## Virtual Hot Trot 5K Run/Walk

*Organized by the SNMMI-TS PDEF*

The Hot Trot 5K is back this year, in a virtual way. Proceeds will benefit the SNMMI-TS Professional Development and Education Fund, supporting the advancement of molecular and nuclear medicine technologists. All registered runners will receive an official race shirt and medal. Sign up by June 30.

# SNMMI 2020 ANNUAL MEETING — VIRTUAL EDITION REGISTRATION

Although registration is required, the Annual Meeting — Virtual Edition is free for SNMMI members. Non-members may either join SNMMI by visiting: **www.snmmi.org/AM2020VE** to attend at no cost or pay a modest fee.

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|---|---|---|---|
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**Current SNMMI Membership year runs through September 30, 2020. Learn more about SNMMI Membership categories.*

**REGISTRATION CLOSES THURSDAY, JULY 9 AT 11:59 PM ET**

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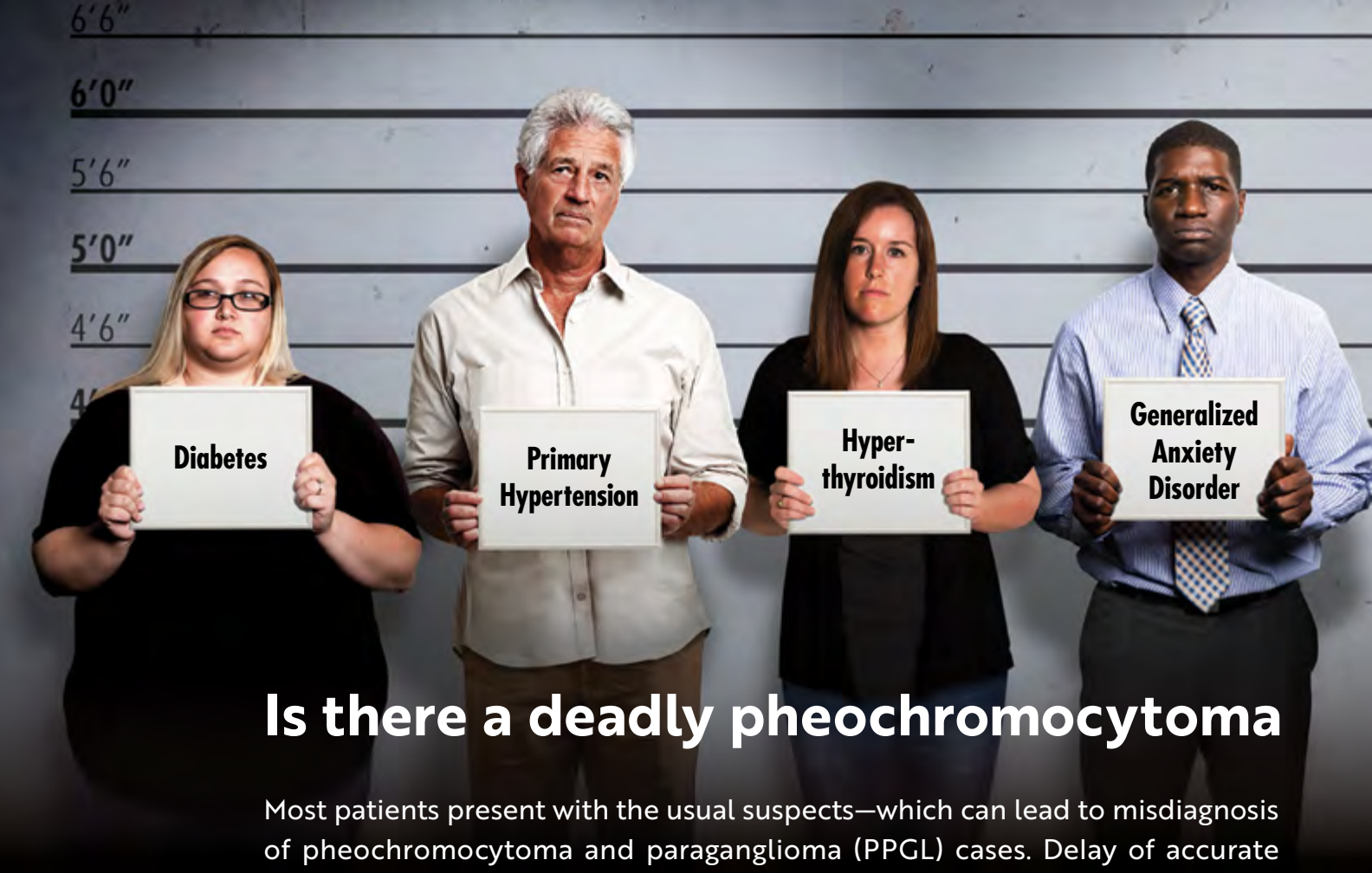


# Is there a deadly pheochromocytoma

Most patients present with the usual suspects—which can lead to misdiagnosis of pheochromocytoma and paraganglioma (PPGL) cases. Delay of accurate diagnosis averages three years. During that time, patients suffer serious symptom burden, and the life-threatening disease can grow.

**Patients need your help making PPGL a prime suspect.**

## 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:** 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. 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, 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.
- **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


# lurking in your lineup?

## When you spot it, you can treat it.

AZEDRA is the first and only FDA-approved treatment for patients 12 years and older diagnosed with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy. **Call 1-844-AZEDRA1 to learn more.**

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 (≥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.

AZEDRA®
iobenguane I 131 injection for intravenous use

**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.**

**References:** **1.** Young WF. Endocrine Hypertension. In: Melmed S, et al. *Williams Textbook of Endocrinology.* 13th ed. Philadelphia, PA: Elsevier; 2016. **2.** Handler J. *J Clin Hypertens.* 2007;9:293-296. **3.** Agarwal V, Kant G, Hans N, et al. *Int J Cardiol.* 2011;153:241-248. **4.** Martucci VL, Pacak K. *Curr Probl Cancer.* 2014;38(1):7-41. **5.** Lefebvre M, Foulkes WD. *Curr Oncol.* 2014;32(1):e8-e17. **6.** Kantorovich V, Eisenhofer G, Pacak K. *Ann NY Acad Sci.* 2009;1148:462-468. **7.** AZEDRA® prescribing information. New York, NY: Progenics Pharmaceuticals, Inc.; 08 2018.

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Progenics Pharmaceuticals®
*Find Fight and Follow®*

# AZEDRA®

## iobenguane I 131 injection for intravenous use

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.

**Table 2: Recommended Dose Modifications of AZEDRA for Adverse Reactions**

| 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:<br>• platelet count less than 25,000/mcL, ANC less than 500/mcL, or life-threatening anemia for more than 7 days<br>• febrile neutropenia<br>• platelet count less than 50,000/mcL with active bleeding |
| Pneumonitis | • 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 |
| Sialadenitis[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[b] | | |
| 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 sialoadenitis, salivary gland pain, and salivary gland enlargement.
[e] Includes abdominal pain, abdominal pain upper, and abdominal pain lower.
[f] Incudes 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, buproprion, duloxetine, mirtazapine, venlafaxine)
- Botanicals that may inhibit reuptake of norephinephrine, 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.

Embryo-Fetal Toxicity

Advise pregnant women and males and females of reproductive potential of the potential risk to a fetus. Advise females to inform their health care provider of a known or suspected pregnancy.

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

Advise male patients with female partners of reproductive potential to use effective contraception during treatment with AZEDRA and for 4 months after the final dose.

Lactation

Advise females not to breastfeed during treatment with AZEDRA and for 80 days after the final dose.

Infertility

Advise females and males patients that AZEDRA may impair fertility.

**Manufactured for:**
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