

Coordinated International Efforts for Reliable Supply of Medical Radioisotopes

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DOE Mo-99 Topical Meeting
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Nuclear Medicine Europe

- **The European Industrial Association for Nuclear Medicine and Molecular Healthcare – “working together to improve molecular healthcare”**
- **33 members, 5 Associate Partners, and 10 reactor operators**
- **Executive Committee and 5 Working Groups:**
 - **Security of Supply (SoS WG)**
 - **Transport Experts**
 - **Communications**
 - **Therapy**
 - **Regulatory Affairs**

Security of Supply (SoS) Working Group Mission/Objectives

- Nuclear Medicine Europe members and research reactors (RR) which irradiate targets for medical isotope production.
- Ensure isotope production continuity and supply of radiopharmaceutical imaging and therapy products to patients.
 - Coordinate research reactors operating schedules to provide adequate global coverage during planned reactor shutdown periods for refuelling and maintenance.
 - Respond to potential or actual disruptions in production (Emergency Response Team, ERT).
- Exchange info on medical isotope developments between radiopharm manufacturers and RR operators; discuss issues of common concern.
- Coordinate within NMEu; consult and communicate with external stakeholders (EU Observatory; SAMIRA/ERV; OECD/NEA, IAEA).

SoS WG Activity

- **Virtual meetings only in 2020 (June, November) and 2021 (June, December) for reactor schedule coordination and other issues.**
 - ERT – Covid, March-May 2020
 - ERT – OPAL, March-April 2021
- **Participated/contributed to EU SAMIRA studies (2020-2021).**
- **Communications in fall 2021 to EU re: I-131 supply, IRE HEU outage.**
- **24 Jan-21 March 2022 HFR unplanned outage**
 - ERT meetings and 9 written communications.
- **Discussions with and communications to EU regarding Russian isotope supply and potential sanctions**
- **SNMMI Vancouver, June 2022 (1st in-person meeting since 2019).**
 - 2022/2023 Reactor Schedule Coordination (2022 Rev. 4/5; 2023 Rev. 0/1)

Spotlight - COVID-19 Response

- SoS WG/ERT met weekly beginning 9 March 2020 thru 28 May 2020; exchanged info – especially transport situation - and shared best practices.
- The medical radioisotope supply chain demonstrated resiliency.
- Patients were able to receive life-saving diagnostic and therapeutic isotopes despite the various challenges posed by the pandemic.
- Certain regions were impacted by reduced and/or re-scheduled deliveries.
- However, global Mo-99 production continued un-interrupted.
- The Mo-99 supply chain – medical isotope target production; research reactors; Mo-99 processing facilities; Tc-99m generator production facilities and logistics/transportation providers took actions to protect workforces from COVID-19 to ensure continuity of service.
- Greatest challenge was in the global transport of Mo-99 and Tc-99m generators, due to the major disruptions and reductions in commercial air passenger (and related cargo) service.
- Security of supply of medical isotopes was maintained by the sustained efforts of many institutions, companies, and employees during this difficult and challenging period.

SoS WG Current Activities

- **Communication to EU Observatory/external stakeholders re: I-131 situation for Fall-Winter 2022**
 - MARIA research reactor maintenance September 2022 thru February 2023
- **Virtual meeting 6 September to discuss potential adjustments to 2023 Rev. 2; letters subsequently sent requesting schedule changes.**
- **SoS WG in-person meeting, 17 October, EANM Barcelona – 2023 schedule finalized.**
- **Continued monitoring concerning potential Russia stable and radioactive isotope sanctions.**
- **Provide advice/assistance for SAMIRA Action Plan/European Radioisotope Valley Initiative re: emerging isotope requirements.**

Conclusions

- **Coordinated nuclear medicine industry and stakeholder efforts have played a critical role in efforts to strengthen the Mo-99 and other isotopes supply chain.**
- **Industry-supported measures have been successful in improving the reliability and security of supply of Mo-99 and other isotopes.**
- **Attention required for new developments in nuclear medicine (theranostics/therapy) and interaction with efforts such as European Radioisotope Valley Initiative.**



DOE Mo-99 Topical Meeting

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IAEA HQ Vienna

October 6-7, 2022



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**Nearly 50 years of
Technetium Tc-99m
generator
manufacturing
expertise**



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radiopharmaceutical
imaging agent in the
U.S.¹**



**#1 ultrasound
enhancing agent
used in the U.S.
for 20 years²**



**Best-in-class
PSMA PET
imaging agent
for prostate
cancer**

(1) Sestamibi was the most used radiopharmaceutical in the U.S. based on procedure volume, DRG 2019 Imaging Market Guide.

(2) DRG Echo Monthly Monitor.

Lantheus Business Groups

Portfolio categories:

1

Precision
Diagnostics



Xenon
Xe 133 Gas



2

Radiopharmaceutical
Oncology



1095*

LMI 1195*

3

Strategic Partnerships
& Others

Pharma Services: Biomarkers

NTI-1309* RATIO NM-01* reflexion**



Microbubble Partnerships***



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Product candidates; ** Revenue will be reported under the Radiopharmaceutical Oncology category; *** Revenue will be reported under the Precision Diagnostic category; **** Revenue will be reported under the Strategic Partnerships & Other category



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Radioactive Diagnostic Agent

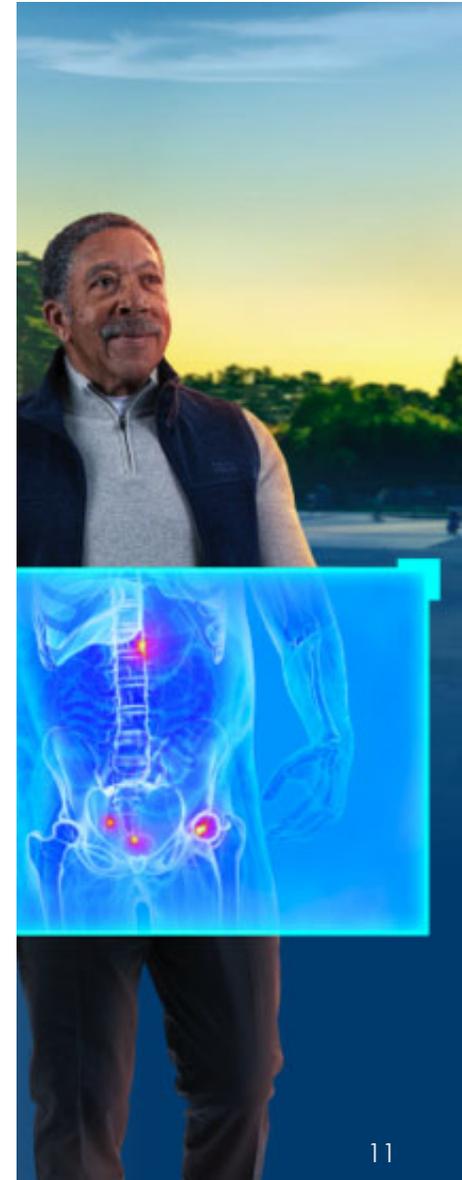
PYLARIFY® (piflufolastat F 18) Injection is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer:

- with suspected metastasis who are candidates for initial definitive therapy.
- with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.

Radiopharmaceutical Oncology

PYLARIFY® [package insert]. North Billerica, MA: Progenics Pharmaceuticals, Inc., a Lantheus company.

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Medical Radioisotope Update

Current Mo-99 and Radiopharmaceutical Market/Recent Developments:

- Mo-99 supply has been reliable and sufficient:
 - global supply chain had adequate capacity to adjust to unplanned February-March HFR outage (no impact to Lantheus).
 - MARIA research reactor began six month planned maintenance at beginning of September, reduces global I-131 supply.
- Lantheus Mo-99 producers have largely completed conversion to LEU.
 - Due to our balanced and diversified supply chain, Lantheus remains confident in Moly supply despite planned and unplanned outages at individual reactors.
 - IRE I-131 LEU conversion still underway.
- Russia:
 - logistics and financial sanctions have complicated export of Russian isotopes (no impact to Lantheus).
 - Inflation Reduction Act promotes increased U.S. domestic isotope production.

Domestic Mo-99 and radioisotopes:

- Lantheus pleased to see SHINE construction progressing; logistics & regulatory preps.
- Tc-99m will continue to be an important imaging modality even as demand for theranostic radiopharmaceuticals increases (e.g. PMSA for prostate cancer Rx/Dx).