

#### SECURITY OF RADIOISOTOPE SUPPLY

## ADDRESSING SOCIETAL CHALLENGES THROUGH ADVANCING THE MEDICAL, INDUSTRIAL AND RESEARCH APPLICATIONS OF NUCLEAR AND RADIATION TECHNOLOGY

Roy W. Brown

Vice President, Govt. Affairs & Strategic Alliances March 20, 2018

CURIUM – UNITING IBA MOLECULAR AND MALLINCKRODT NUCLEAR MEDICINE LLC

curiumpharma.com



SECURITY OF RADIOISOTOPE SUPPLY

# **OVERVIEW OF CURIUM**

## Curium is the combination of Mallinckrodt's Nuclear Medicine Business and IBA Molecular/CISBIO

3







### OUR SPECT MANUFACTURING FOOTPRINT



Maryland Heights, MO USA

- Expertise in manufacturing reactor and cyclotron based isotopes + cold kits
- State of the art and newest Tc generator line in the US
- 6 cyclotrons able to manufacture Tl-201, Ga-67, Ge-68 and In-111
- Aseptic suite for manufacturing cold kits



Petten Netherlands

- Captive bulk-Moly processing capacity one of the largest in the industry
- Capabilities to manufacture reactor and cyclotron based isotopes + cold kits
- 2 cyclotrons currently manufacturing In-111, I-123, TI-201 and Ga-67
- New state of the art fill-line



Saclay France

- Capabilities to manufacture reactor and cyclotron based isotopes + cold kits
- 3 cyclotrons currently manufacturing Ga-67, I-123
- Sterile manufacturing capabilities for cold kits including terminal sterilisation

Complemented by a network of 20 SPECT Radiopharmacies dispensing mono-doses in Europe



#### HISTORICAL PERSPECTIVE ON MEDICAL RADIONUCLIDES

- The nuclear medicine industry experienced significant shortages of Mo-99 in 2009-2010.
- Since that time the industry has taken significant steps to improve the supply
  - MARIA and LVR-15 reactors were added
  - Significant Mo-99 production capacity has been added
- The industry has adopted the six operating principles of OECD, leading to a more stable supply.



Location of European Medical Radioisotope Production Reactors and Mo-99 Producers



#### THE EC COULD HAVE A MAJOR IMPACT SUPPORTING MEDICAL RADIONUCLIDES

- The Mo-99 producers have faced significant cost increases over the last few years from:
  - The cost of conversion from HEU to LEU, as well as the increased operating costs using LEU to produce Mo-99.
  - The extra cost associated with increasing Outage Reserve Capacity (ORC)
  - Paying for Full Cost Recovery (FCR) from reactor operators
- These changes have increased the cost of Mo-99 production and have forced manufacturers to start increasing Tc-99m generator pricing.
- Reimbursement for nuclear medicine procedures from EC member countries must keep pace with these price increases to protect patient access to one of the most cost efficient imaging modalities.



#### OTHER WAYS THE EC COULD HAVE A MAJOR IMPACT

- The European Strategy Forum on Research Infrastructure (ESFRI)
  - ESFRI establishes the "strategy-led approach to policy making on research infrastructures in Europe."
  - ESFRI has previously supported the MYRRHA and Jules Horowitz reactors.
  - ESFRI support for PALLAS would help their efforts to continue Europe's strong role in medical radionuclide production.
- The world recognizes today most of the innovation in nuclear medicine is coming out of Europe. In order to sustain this the EC could:
  - Support research & development in nuclear medicine.
  - Include nuclear curricula in European universities.