TechneLite® LEU-based Generators

Ira Goldman
Senior Director, Global Strategic Supply and Government Relations

National Academy of Sciences/Russian Academy of Sciences
July 18, 2017
Vienna, Austria
# Lantheus Medical Imaging

## Company Overview

- Lantheus Holdings, Inc. (NASDAQ: LNTH) is the parent company of Lantheus Medical Imaging
- A global leader in innovative diagnostic medical imaging agents
- Products used to diagnose coronary artery disease, congestive heart failure, stroke, peripheral vascular disease and other diseases (one therapeutic - Quadramet®)

## Headquarters
- N. Billerica, Massachusetts

## Offices
- Canada, Puerto Rico

## Global Presence
- ~400+ employees worldwide

## Commercial Products
- Nine

## Development Pipeline
- Next-generation product candidates use Positron Emission Tomography (PET) and Magnetic Resonance Imaging (MRI)
TechneLite® Generator - History

- **99mTc**- generator developed in Brookhaven National Labs in 1958 and commercialized in the mid 1960s
- **99mTc** generator manufactured by LMI and predecessors since 1967
  - New England Nuclear (NEN) introduced Tc-99m Generator based on Mo-99 produced by neutron capture \((^{98}\text{Mo} (n,\gamma)^{99}\text{Mo})\)
  - NDA for generator based on Mo-99 from fission of U-235 \((^{235}\text{U} (n,f)^{99}\text{Mo})\) approved in 1975
- **TechneLite®**, terminally sterilized generator introduced in 1993
- **TechneLite®**, CMS compliant LEU sourced Mo-99 introduced in 2013

1967-1974  
1974-1993  
1993  
2013
Lantheus Medical Imaging
LEU Leadership

• FIRST – to receive FDA approval for LEU Mo-99 in North America:
  – ANSTO: May 2011
  – NTP: September 2010

• FIRST – to commercially sell a generator made with only LEU Mo-99 (December 2010)

• FIRST – to have LEU Mo-99 as a routine part of blended Tc-99m production (May 2011)

• FIRST – to commercially manufacture and regularly distribute CMS non-HEU incremental add-on HOPPS payment compliant generators (beginning January 2013)
LEU Technelite

- Quality and properties of LEU Technelite® generators are equivalent to HEU or blended LEU/HEU Mo-99 generators
  - Radiochemical purity is the same
  - Mo-99 breakthrough is the same
  - Elution efficiency meets specifications

- Tc-99m produced from > 95% LEU content Technelite® generators meets the USP specification

- All aspects of LEU Technelite® generators including product insert and labeling are identical to blended or HEU generator

- Only difference is the “green dot”
LMI LEU Transition

• LEU Mo-99 as proportion of total LMI purchased Mo-99:
  
  2016: 46%  
  2017: 64%

• LEU runs carried out (in whole or part):

  2016: 51/52 weeks  
  2017: 25/26 weeks

• ANSTO capacity increase August 2016 (~2000 Ci/week)

• ANSTO ANM project (3500 Ci/week) - validation 4Q2017

• IRE LEU Conversion – validation late 2017, early 2018
Regulatory Update

- Existing ANSTO facility and NTP LEU FDA approved since 2010-11
- ANSTO ANM will require Prior Approval Supplement (PAS) submission due to new target, process (same as NTP target and process)
  - 3 separate qualification batches, non-commercial (range of generator sizes produced) with kit testing (anionic, ionic, and neutral)
  - data package submission
  - 4 month published statutory review period
- IRE LEU conversion will require submission of Prior Approval Supplement (PAS) to Lantheus TechneLite NDA:
  - each additional reactor (irradiation source) not included in original filing is expected to require additional FDA filing
- Health Canada 225-day statutory review period is longer than FDA
- FDA and Health Canada have worked diligently in the past to expedite reviews and approvals
Xe-133

• Xe-133 used in U.S. for pulmonary imaging
• Lantheus announced new strategic agreement on January 21, 2015 with IRE for supply of Xe-133 gas
• IRE provides unprocessed radiochemical Xe-133 to Lantheus for processing and finishing
• FDA approval received on June 10, 2016
• First commercial shipment June 30, 2016
• IRE replaced NRU beginning in November 2016
• Additional diversification options being pursued
• LEU-based Xe-133 development advancing
Conclusions

• Lantheus has taken a leadership role in use of LEU Mo-99 in its TechneLite® generator supply chain

• Commercial adoption of LEU TechneLite® generators is steadily increasing

• LEU contributes to enhanced global nuclear security and creates foundation for more diversified, secure, reliable future supply of Mo-99

• Lantheus and IRE are working diligently to secure future Xe-133 supply

TechneLite® and corporate logo display are registered trademarks of Lantheus Medical Imaging, Inc.
Thank you

Questions?