



## **TechneLite<sup>®</sup> LEU-based Generators**

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# 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

- $^{99m}\text{Tc}$ - generator developed in Brookhaven National Labs in 1958 and commercialized in the mid 1960s
- $^{99m}\text{Tc}$  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<sup>®</sup> 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<sup>®</sup> generators meets the USP specification**
- **All aspects of LEU Technelite<sup>®</sup> 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<sup>®</sup> generator supply chain**
- **Commercial adoption of LEU TechneLite<sup>®</sup> 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**

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# Thank you

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Questions?