Securing Mo-99 Supply for LEU TechneLite® Generator Production

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DOE Mo-99 Topical Meeting
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# Lantheus Medical Imaging

## Company Overview
- Lantheus Holdings, Inc. (NASDAQ: LNTH) is the parent company of Lantheus Medical Imaging Inc.
- 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

- $^{99m}$Tc- generator developed in Brookhaven National Labs in 1958 and commercialized in the mid 1960s
- $^{99m}$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 ($^{98}$Mo (n,γ) $^{99}$Mo )
  - NDA for generator based on Mo-99 from fission of U-235 ($^{235}$U (n,f) $^{99}$Mo) approved in 1975
- TechneLite®, terminally sterilized generator introduced in 1993
- TechneLite®, CMS compliant LEU sourced Mo-99 introduced in 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 (LEU) incremental add-on HOPPS payment compliant generators (since 1/7/2013)
Technelite LEU

Circling the globe… to bring TechneleLite® to you

Focused on Your Future

- Globally diversified and balanced supply chain
- Supply agreements with IRE, NTP and ANSTO Mo-99 processors

Spearheading Low-Enriched Uranium (LEU)-sourced Mo-99 in the U.S.

- Strategy in place for a consistent and increasing supply of LEU-sourced Mo-99
- First to gain FDA approval to use LEU-sourced Mo-99 in our TechneneLite® generator manufacture on June 25, 2009
- First to offer a Center for Medicare and Medicaid Services (CMS) compliant LEU manufactured technetium-99m generator (TechneneLite®) on January 7, 2013

Same Quality and Reliability

- LEU TechneneLite® generators are equivalent in the elution process and provide the consistent performance you value
- LEU TechneneLite® generators are available in our standard sizes

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LEU Supply

- Dedicated, weekly LEU TechneLite\textsuperscript{®} generator runs 2013-17 (through 06-SEP-2017)

- LEU Mo-99 as proportion of total LMI purchased Mo-99 (2017 projected)

- ANSTO capacity increase to 2250 Ci/week in place since August 2016

- ANSTO ANM project (3500 Ci/week) validation expected late 2017, early 2018

- IRE LEU conversion: validation runs planned early 2018
Mo-99 Supply Planning Process

• Mo-99 supply planning is a continuous process

• Intensive Communication

• Increased Focus on In-Bound Logistics

• Proactive Reactor Schedule Review/Monitoring
LEU TechneLite® generators shipped activity
LEU TechneLite®

- Lantheus continues to promote uptake of LEU generators
  - increasing number of Private Payers are reimbursing use of LEU

- Lantheus LEU Webinar:
  - Provides a Nuclear Pharmacy’s 2-year experience
    • Implementation into pharmacy operation
    • Education of End Users in market
    • Delivery of LEU doses to End Users
  - Provides an End Users’ experience
    • Implementation into operation
    • Reimbursement process

- UPPI “LEU Walk” continues
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

• LEU TechneLite® generators poised for significant increase in 2017 with projected all-LEU Mo-99 supply

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

• Anticipate full conversion to LEU in 2018

• Lantheus and IRE have secured Xenon-133 supply
Thank you

Questions?