Update on LEU TechneLite® Generators

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Mo-99 Topical Meeting
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Lantheus Medical Imaging (LMI)

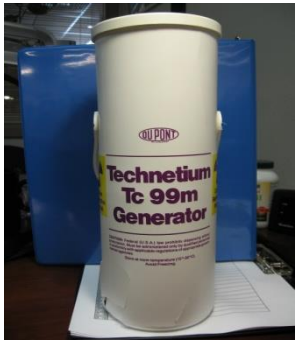
Company Overview	• A global leader in innovative diagnostic medical imaging agents • Pharmaceutical imaging agents used to diagnose coronary artery disease, congestive heart failure, stroke, peripheral vascular disease and other diseases
Headquarters	• N. Billerica, Massachusetts
Offices	• Canada, Puerto Rico, Australia
Commercial Products	• 10
Development Pipeline	• Three next-generation product candidates that 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**

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 Jan. 7, 2013)**

Lantheus Medical Imaging adds the innovative

LEU TechneLite®

(Technetium Tc 99m Generator)

to our Nuclear Medicine Portfolio

Available NOW!

Lantheus Medical Imaging®

LEU TechneLite® Manufacture

- **Dedicated, weekly LEU TechneLite® generator runs 2013-15 (87.3%)**
  - **2013 – 46 weeks**
  - **2014 – 42 weeks**
  - **2015 – (34 out of 35) (thru August 31) - 97%***
- **Validated cleaning process after each run ensures manufacturing line is clean and meets the CMS >95% LEU content criteria**
- **TechneLite® LEU generators marked as eligible for CMS add-on HOPPS payment by circular green sticker affixed to top of generator can and unique item number**
- **LEU TechneLite® generator segregation and identification**
  - manufacturing batch records - different code for LEU Mo-99 than HEU Mo-99
  - specific catalog/item number in the Lantheus product catalog and systems (18000-ML versus 18000-M for HEU generator)
  - identifying item number is also on packing, shipping documents and invoice
  - lot number unique identifier – with an "A" incorporated (non-HEU generator - M123456A)
- **Certification document provided by LMI to customers receiving an LEU TechneLite® generator**

***HEU shipped in error instead of LEU**

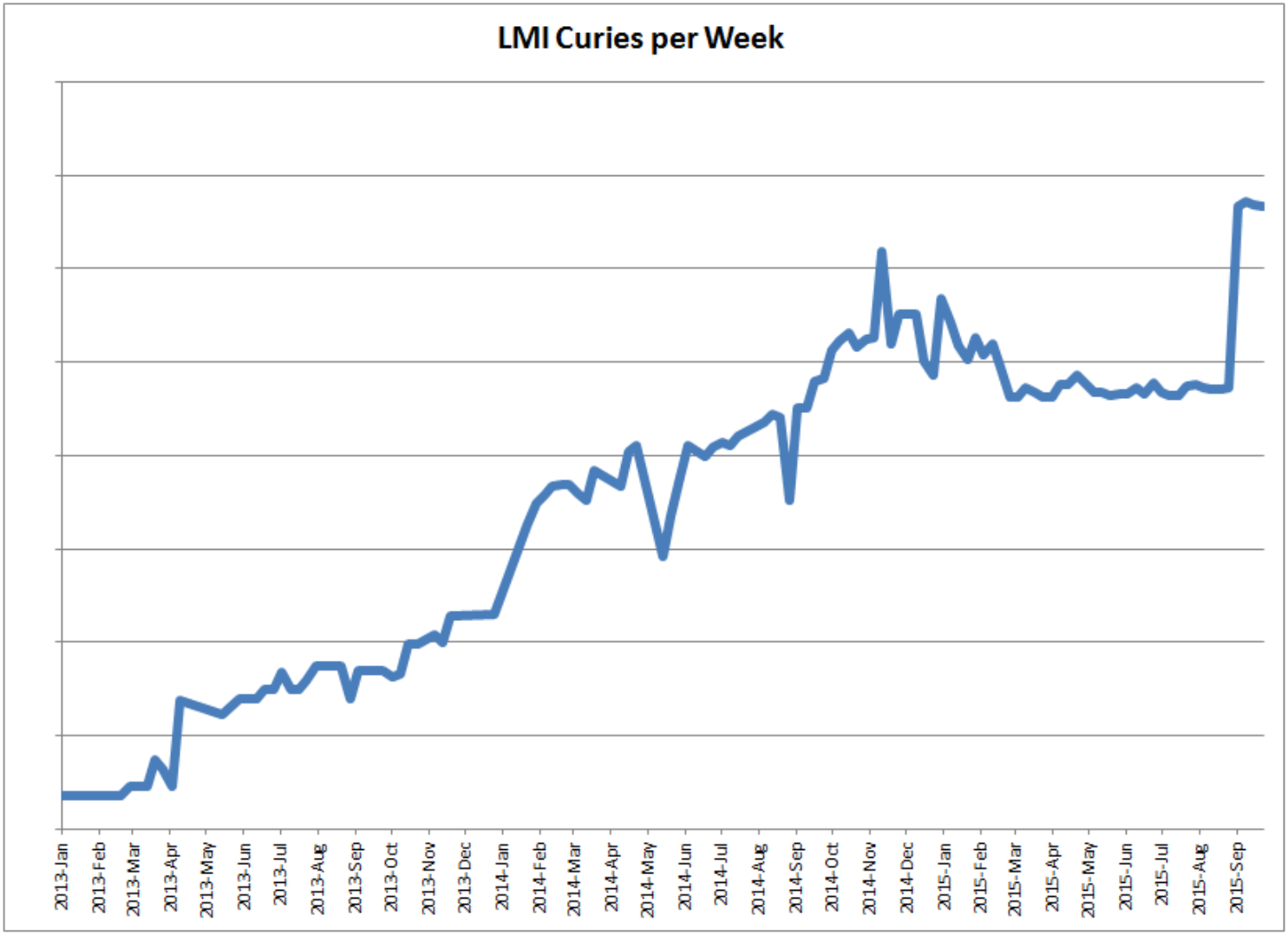
LEU Technelite® Features

- **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 (see chart)
- **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”**

LEU TechneLite® Commercial Status

- **Substantial misperceptions and misunderstandings continue to persist in the market about LEU availability and reliability, CMS add-on payment, etc.**
- **Lantheus interacting with customers to promote uptake of LEU generators**
  - Adoption is increasing at Rx level
    - new LEU dose business mostly from VA Hospitals (leveled off)
  - CMS data demonstrates steadily rising claims, though still small
- **Lantheus continues to provide information to increase LEU knowledge at hospitals (i.e. August 2014 webinar and planned 2015 webinar)**
- **Continue to assess LEU supply chain ability to service additional or different days of LEU TechneLite® manufacture**
- **Production volume increases and day of manufacture changes dependent upon demand and customer committed orders**

LEU TechneLite® generators shipped activity



Full Transition to LEU

- **LEU Mo-99 as proportion of total LMI purchased Mo-99:**

  2013: 20% 2014: 25% 2015 ~35%

- **LEU supply chain issues experienced in first half of 2014 were effectively addressed and remedied**

- **ANSTO plans capacity increase in existing plant starting June 2016 to 2250 Ci/week**

- **ANSTO ANM project (3500 Ci/week) commissioning 2H2016.**

- **IRE LEU conversion expected mid-year 2016 (hot runs in fall 2015; validation and qualification first half 2016)**

- **Lantheus currently anticipates a full transition to LEU by end of November 2016 (assuming IRE LEU conversion is on schedule)**

Full Transition to LEU - Barriers

- **Technical: none**
- **Market: already described in commercial status slide**
- **Logistical:**
  - commercial cargo transport from Australia, Belgium, and South Africa poses challenges; occasional delays due to unexpected administrative issues
- **Regulatory:**
  - ANSTO and NTP LEU sources already FDA approved
  - IRE LEU conversion will require submission of Prior Approval Supplement (PAS) to Lantheus Technelite NDA:
    - 3 separate qualification batches, non-commercial (range of generator sizes produced) with kit testing (anionic, ionic, and neutral)
    - data package submission
    - 4 month statutory review period
    - each additional reactor (irradiation source) will require further FDA filing (TBD)
  - ANSTO ANM will likely also require PAS due to new target, process (same as NTP target and process)
  - FDA has worked diligently in the past to expedite reviews and approvals

LEU TechneLite® and Nuclear Pharmacies

- **Lantheus LEU Webinar has been filmed for September roll out:**
  - Provides a Nuclear Pharmacy's 2-year experience
    - Implementation into pharmacy operation
      - Operation changes
      - System changes
    - Education of End Users in market
    - Delivery of LEU doses to End Users
  - Provides an End Users' experience
    - Implementation into operation
      - Operation changes
      - System changes
    - Reimbursement process

  - NOT AS DIFFICULT AS OFTEN PORTRAYED

- **UPPI "LEU Walk," implementing in 30+ pharmacies**

Xe -133

- **Xe-133 used in U.S. for pulmonary imaging**
- **NRU is currently the only source of bulk Xe-133 gas; Lantheus only Xe-133 pharmaceutical product supplier in U.S.**
- **Lantheus announced new strategic agreement on January 21, 2015 with IRE for future supply of Xe-133 gas**
- **IRE will provide unprocessed radiochemical Xe-133 to Lantheus for processing and finishing**
- **Development and commercialization work in process, good progress to date**
  - Type A transport container designed and fleet being fabricated
  - Argonne National Lab provided analytical assistance
- **Regulatory review and approval will be required**
- **Lantheus estimates commercial production will occur in 2016**
- **Investigating additional diversification options and LEU-based Xe-133**

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 secure, reliable future supply of Mo-99**
- **Lantheus and IRE are working diligently to secure future Xe-133 supply**

Thank you

Questions?