Next Generation Mo-99 Production: SHINE Update

SHINE Medical Technologies

Health. Illuminated.
SHINE Snapshot

**SHINE has made leading progress toward U.S.-based Mo-99 production**

- One of few projects aggressively pursuing new irradiation and processing infrastructure
- Prototype facility located in Monona, WI
- Current key activities
  - **Regulatory:**
    - NRC construction permit (expected early 2016)
  - **Commercial:**
    - Two supply agreements executed; others under negotiation
  - **Fundraising:**
    - Over $25M private investment to date
    - Over $40M total
- Leading efforts to establish domestic fission-based isotope supply
SHINE Technology Overview

A modernized approach to making Mo-99

• Integrated production and refining

• SHINE irradiation unit is a hybrid
  • Accelerator-based D-T neutron generator acts as “spark plug”
  • Neutrons multiply in subcritical uranium sulfate solution, allowing for very high yield

• Plant capacity of 4000 6-day Ci/week

• Fission Mo allows use of existing supply chain, no changes to pharmacy practices

• Cost effective approach

• Fission process ensures access to other isotopes, including I-131 and Xe-133
Technology Milestones

*Major technical risks have been eliminated*

- Accelerator/Neutron Generator
  - Plant-scale accelerator demonstrated at full scale
  - 99% uptime on 24 hour run
  - Thousands of hours logged on similar accelerators

- Target/Chemistry
  - High process yields demonstrated
  - Target recycling demonstrated
  - Production of Mo-99 to commercial purity standards at Argonne

- Many other technical demonstrations complete
  - Other plant systems are variants of systems that have been in use for decades
Facility Design and Site Progress

- Preliminary design completed early 2013
- Approximately 55,000 sq. ft. hardened production facility
- 8 irradiation units – ensures high reliability, flexible production schedule
- Independent hot cell chains further increase reliability and flexibility
Facility Design Progress

*Design maturity sufficient for construction permit, including safety significant features*
Regulatory

*SHINE noted as model applicant and “moving at the speed of light” by NRC*

- Submitted construction permit application in early 2013
- Have moved rapidly through application process
- Draft Environmental Impact Statement issued in May

- Construction permit issuance expected early 2016

“The Commission has approved publication of a Direct Final Rule as one step … addressing the construction permit application from SHINE. Others are not as far along in the process.”

-- Allison M. Macfarlane, NRC Chairman, August 27, 2014
<table>
<thead>
<tr>
<th>Milestone</th>
<th>Date</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receipt of Construction Permit Application (Part 1 of 2)</td>
<td>March 2013</td>
<td>Complete</td>
</tr>
<tr>
<td>Receipt of Construction Permit Application (Part 2 of 2)</td>
<td>May 2013</td>
<td>Complete</td>
</tr>
<tr>
<td>Docketing of Construction Permit Application (Part 1 of 2)</td>
<td>July 2013</td>
<td>Complete</td>
</tr>
<tr>
<td>Environmental Scoping Meeting</td>
<td>July 2013</td>
<td>Complete</td>
</tr>
<tr>
<td>Environmental Site Audit</td>
<td>August 2013</td>
<td>Complete</td>
</tr>
<tr>
<td>Issuance of Request for Additional Information on Environmental Report</td>
<td>August 2013</td>
<td>Complete</td>
</tr>
<tr>
<td>Docketing of Construction Permit Application (Part 2 of 2)</td>
<td>December 2013</td>
<td>Complete</td>
</tr>
<tr>
<td>Issuance of Request for Additional Information on Preliminary Safety</td>
<td>September 2014</td>
<td>Complete</td>
</tr>
<tr>
<td>Analysis Report and Environmental Report</td>
<td>September 2014</td>
<td>Complete</td>
</tr>
<tr>
<td>Issuance of Supplemental Requests for Additional Information on</td>
<td>January 2015</td>
<td>Complete</td>
</tr>
<tr>
<td>Preliminary Safety Analysis Report and Environmental Report</td>
<td>March 2015</td>
<td>Pending</td>
</tr>
<tr>
<td>Completion of Draft Environmental Impact Statement</td>
<td>May 2015</td>
<td>Complete</td>
</tr>
<tr>
<td>Advisory Committee on Reactor Safeguards Subcommittee Meetings</td>
<td>June-Sept 2015</td>
<td>Underway</td>
</tr>
<tr>
<td>Advisory Committee on Reactor Safeguards Full Committee Meeting</td>
<td>October 2015</td>
<td>Pending</td>
</tr>
<tr>
<td>Publication of Safety Evaluation Report</td>
<td>October 2015</td>
<td>Pending</td>
</tr>
<tr>
<td>Publication of Environmental Impact Statement</td>
<td>October 2015</td>
<td>Pending</td>
</tr>
<tr>
<td>Mandatory Hearing on Construction Permit Application</td>
<td>December 2015</td>
<td>Pending</td>
</tr>
</tbody>
</table>
Commercial Progress

Market conditions continue to provide unique opportunity for SHINE

• Supply agreements signed with GE Healthcare and Lantheus Medical Imaging in 2014
  • Only definitive agreements with a U.S.-based producer
  • First supply agreements that don’t rely on government-funded infrastructure
• Additional supply agreements under negotiation

“GE Healthcare is very pleased to have entered into a long-term supply agreement with SHINE. The technology represents a significant, safe and viable option for the production of molybdenum-99 in the future. We believe SHINE will help secure supply for global medical communities and their patients.”
  ❖ Jan Makela, GM of GE Healthcare Life Sciences Core Imaging
  April 4, 2014

“Strategic sourcing of Mo-99 is a key priority at Lantheus, and our agreement with SHINE is one important step in our ongoing proactive efforts to strengthen and diversify our supply to ensure the nuclear medicine community and patients have reliable access to TechneLite in the future.”
  ❖ Jeff Bailey, President and Chief Executive Officer of Lantheus Medical Imaging
  November 3, 2014
Path Forward

Industry leading progress has been made, focus is now on securing construction financing

- Invested 5+ years and over $40M so far:
  - ~$14 million federal
  - Almost $30 million non-federal
- Industry-leading accomplishments:
  - Proven technology
  - Proof of commercial viability through customer contracts
  - Strong regulatory track record
- Plant will be first new infrastructure to produce Mo-99 and other isotopes in the US—will not rely on government-subsidized, aging, HEU-fueled infrastructure
- Pursing multiple avenues to secure construction financing—time to market roughly three years from full financing
- Full use of NNSA cost-share authority provided by AMIPA, would unlock private match immediately
  - Up to 80/20 cost share for R&D
  - Up to 50/50 for construction
- Consistent with NSAC recommendations for the past two years
In Conclusion...

**SHINE’s technology and processes have several clear competitive advantages**

**Demonstrated, Patented Technology**
- Accelerator technology replaces nuclear reactor
- Avoids the use of HEU entirely
- Reusable liquid target allows simplified production and recovery
- Proprietary process combines a number of already-proven technologies

**Superior Economics**
- U.S.-based, avoids significant transportation loss
- Operating costs much lower than reactor
- Substantially reduced material costs: no nuclear reactor, reusable target

**Compatible with Existing Market**
- Product fits seamlessly into the existing supply chain
- Utilizes existing technetium generators
- Market validation – supply agreements executed with two of the largest Mo-99 buyers
Questions?

We appreciate your time and encourage follow up discussions

Contact Information:
Katrina Pitas
VP, Business Development
608.210.1060
Katrina.Pitas@shinemed.com