Ac-225 Program Overview

Workshop on Standards and Measurements for Alpha Emitting Nuclides in Therapeutic and Nuclear Medicine

Daniel J. De Vries, Ph.D.
Senior Director, Medical Radioisotope Product Development
Highly experienced leadership team with decades of proven success
• Fully supported by NorthStar’s Board and Senior Leadership
• Dedicated resources
• Multiple Supply Agreement in place with others expected in the rest of 2024

100% owned manufacturing infrastructure
• Designed for global supply and distribution
• Proven foundation in producing cGMP radioisotopes - >2M+ patient doses served
• Multiple FDA approvals and inspections

Secure Source Material and Long-lead Items
• Long lead items secured and propriety technology in progress to support large scale commercial manufacturing
• Multiple sources and sufficient quantities of starting material to meet future production needs

Facilities designed with reliability, redundancy, flexibility & scalability as a priority

• Third IBA TT-300 HE Rhototron installed
• Intense focus on
  > Strategic Partnerships
  > Facilities design & construction
  > Waste management
  > Radon mitigation
• Facilities designed with reliability, redundancy, flexibility & scalability as a priority
Industry Leadership

Asset Overview

One of a kind facility and equipment specific to the Industry

Radioisotope Technical Expertise
SME’s

HPGe, ICP-MS, MP-AES, LaBr3, LSC, radio-HPLC, IC, Hot Cells, Glove Boxes, Isolators, RadLabs, MicroLabs

3 Ph.D. Physicists / Nuclear Engineers
8 Ph.D. Radiochemists
6 Nuclear Pharmacists
Dozens of Engineers and support staff

Governance Compliance

Robust QA/RA Programs

Excellent Rapport and Record with Governing bodies

Multiple, sequential FDA approvals

7 successful FDA inspections

Extensive Documentation and SOP process

Appropriate radioisotope product licensing Storage/Waste

Awards and Industry Recognition

1. Frost & Sullivan 2020 Visionary Innovation Leadership Award
2. DOE’s Outstanding Achievement Award
3. WCI (World Council of Isotopes)
   Recognized for outstanding contributions to isotopes
4. ABC of Wisconsin’s Projects of Distinction
   Excellence in Construction Gold Award
5. R&D Top 100 Award for Innovation
6. EPA-Green Challenge Award Nominee
7. Packaging Innovation award
8. Isotope Processing Facility Award

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NorthStar will be the first and only U.S. company housing commercial-scale, multi-radioisotope production and radiopharmaceutical development services on the same campus, enabling collaborator companies to realize logistical, regulatory, and cost benefits.
55 acre Campus Designed with a Purpose

Living our Mission to Provide Patients Global Access to Game-Changing Radiopharmaceuticals

- n.c.a. Ac-225 Production facility (construction underway)
- Accelerator Production facility
- cGMP-Compliant Manufacturing facility
- Isotope Processing facility
- Corporate HQ

Additionally, two R&D facilities in Madison, WI (including an R&D RAM License location)
NorthStar’s Actinium Manufacturing Process

Ra-226 Target
Ra-226 Source Material

Ra-226 Reprocessing
Recover and Reuse
Reclamation is an integral part of NorthStar’s process - aids in maintaining costs while reducing the reliance on external suppliers for such a scarce isotope

Ac-225 Generator Approach
n.c.a. Ac-225
NorthStar’s Rhototron + process chemistry + generator approach eliminates actinium impurities (Ac-226 / Ac-227) Decoupling irradiations from generator processing (milking) provides Ac-225 to customers even during accelerator maintenance periods / outages

NorthStar’s High Energy Electron Accelerator (125 kw) has the ability to produce up to 200 Ci/year

Flexible Ra-225 Production
Optimize Ra-226 usage via adjustable accelerator power, customized target mass, and variable irradiation times to meet changing demand

Flexible Ordering
Multiple generators maximize flexibility in meeting customer demand (available 7 days/week)

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Actinium Generator Process

Source Farm (liquid radium solutions)

New radium source added to Source Farm

Spent radium sources removed for reprocessing

Radium source(s) passed through separation process

Radium source(s) returned to Source Farm

Bulk n.c.a. Ac-225 aliquoted into customer vials

Radium Sources
- Aqueous solution of Ra-225
- Ac-225 grows in over time
- New source produced weekly

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High Level Timeline for Ac-225 Production

*We are working to further optimize our time to market*

- **SEPT 2021**: Facility groundbreaking
- **NOV 2021**: Orders placed for accelerator and essential long-lead items
- **EARLY 2022**: Construction underway
- **Q3 2024**: Initial production of radiochemical grade Ac-225
- **Q1 2025**: Drug Master File submitted to FDA
NorthStar demonstrates their commitment to provide commercial quantities of Ac-225.

NorthStar has the technology, experience and resources to provide Ac-225 per our projected timeline.

Proven and ongoing experience with all regulatory agencies.

Radiochemical grade Ac-225 potentially available late Q3 2024 – GMP Q1-Q2 2025.
Please Visit Our Website!

www.northstarnm.com