

MOLYBDENUM-99

FDA approves NorthStar's Tc-99m generator

Approval of the RadioGenix System makes NorthStar the first U.S. company to supply the medical radioisotope in more than 25 years.

Saying that it is taking steps to ensure a stable and secure supply of a critical radioactive imaging product used to detect potentially life-threatening diseases, the U.S. Food and Drug Administration on February 8 approved NorthStar Medical Radioisotope's RadioGenix System. The system is a radioisotope separation platform used to produce the widely used medical radioisotope technetium-99 from non-uranium-produced molybdenum-99.

Beloit, Wis.-based NorthStar is one of several companies, including SHINE Medical Technologies, also of Wisconsin, and Northwest Medical Isotopes, based in Corvallis, Ore., that are seeking to build a domestic supply of Mo-99, the parent isotope of Tc-99m. Previously, Mo-99 could only be produced from enriched uranium by several facilities outside of the United States, leaving the U.S. vulnerable to possible shortages and supply chain issues.

Following the passage of the American Medical Isotopes Production Act of 2012, which contained provisions to eliminate the use of high-enriched uranium for medical isotope production and encouraged the development of domestic supplies of Mo-99 and associated isotopes, multiple federal agencies have been working with industry to develop a technology that helps minimize the industry's dependence on HEU and brings the supply chain within the United States. Partial funding for NorthStar's technology was provided by the Department of Energy's National Nuclear Security Administration.

"With the FDA's approval of the RadioGenix System, NorthStar can begin providing its customers with a reliable and

environmentally friendly supply of the Mo-99 radioisotope for the United States," George P. Messina, chairman and chief executive officer of NorthStar, said in a statement. "As the first, and thus far, only company to achieve the objective of being the first U.S. producer of Mo-99 in more than 25 years, we are extremely proud to pioneer domestic production of Mo-99 that is independent of uranium-based product."

According to NorthStar, its processes are based on proven, well-established principles, yet mark a significant technological advancement period. The company's non-uranium Mo-99 production process involves three phases: neutron capture production of Mo-99 using natural molybdenum, neutron capture production of Mo-99 using enriched Mo-98, and accelerator (neutron knock-out) production of Mo-99 using enriched Mo-100. NorthStar said that it expects to begin shipping product to customers within several weeks of the FDA's approval.

The Nuclear Regulatory Commission is issuing guidance and will license the RadioGenix System to enable the Tc-99m it produces to be used for its medical purpose. Tc-99m is a diagnostic agent that is used by health care professionals to detect potential diseases, such as coronary artery disease and cancer, and to evaluate lung, liver, kidney, and brain function. When used with the appropriate diagnostic scanner device, such as a SPECT imaging system, the Tc-99m emits signals that are captured to produce an image of internal organs to detect various medical problems and contribute to diagnosis and treatment decisions. **NW**