**U.S. FDA Approves NorthStar Medical Radioisotopes’ RadioGenixTM System (Technetium Tc 99m Generator) for Non-uranium Sourced Molybdenum-99 (Mo-99) Production of Imaging Isotope Technetium-99m (Tc-99m)**

***- Enables domestic Mo-99 supply produced without uranium for U.S. healthcare -***

***- First U.S. source of medical radioisotope Mo-99 in more than 25 years -***

**BELOIT, Wis. – February 8, 2018 –** NorthStar Medical Radioisotopes, LLC, (NorthStar) a company involved in the production and distribution of radioisotopes used for medical imaging, today announced that the U.S. Food and Drug Administration (FDA) has approved the RadioGenixTM System, an innovative, high tech radioisotope separation platform indicated for use in producing the widely used medical radioisotope technetium-99 (Tc-99m) from NorthStar’s non-uranium based molybdenum-99 (Mo-99). The RadioGenixTM System is indicated as “a technetium Tc 99m generator used to produce sterile, non-pyrogenic Sodium Pertechnetate Tc 99m Injection.”

There has been no U.S. production of Mo-99, the parent isotope of Tc-99m, for more than 25 years. The supply of Mo-99 has been subject to frequent and sometimes prolonged interruptions, disrupting and often delaying the diagnosis and treatment of patients in need of medically important diagnostic tests that require the use of this radioisotope. Furthermore, current bulk production of Mo-99 is based on enriched uranium which poses significant environmental concerns.

“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,” said George P. Messina, Chairman and CEO of NorthStar Medical Radioisotopes. “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. The approval by the FDA will reduce the U.S. healthcare system’s reliance on fragile foreign supply of Mo-99 and the use of enriched uranium target material. The RadioGenix System allows for automated, on-site separation and preparation of U.S. Pharmacopeia (USP) Sodium Pertechnetate Tc 99m Injection from Mo-99. The RadioGenix is also a platform technology that has the potential ability to apply its separation capabilities at the point-of-care to other radioisotopes in the future, including therapeutic isotopes such as actinium-225/bismuth-213 (which will require FDA approval). Bringing RadioGenix successfully to the U.S. market has been made possible through the support of our private commercial investors and the U.S. Department of Energy’s National Nuclear Security Administration and is the first step in our commitment to provide innovative products and solutions for the nuclear medicine community and the patients it serves. The RadioGenix System is the first major technical advancement in years in the nuclear medicine market, especially for the production of Mo-99.”

“NorthStar’s processes are based on proven, well-established principles, as exemplified by our neutron capture production process, and marks a significant technological advancement to current technology,” said James T. Harvey, Ph.D., Senior Vice President & Chief Science Officer of NorthStar Medical Radioisotopes. “By utilizing state-of-the-art chemical processing to achieve domestic Mo-99 production without the use of any uranium target material, we can meet appropriate Pharmacopeia standards for Mo-99. Additionally, the Mo-99 produced by NorthStar’s RadioGenix System, a proprietary one-of-a-kind automated radioisotope separation system that utilizes a worldwide patented on-board, on-demand, point-of-use sterilization system to produce USP compliant Sodium Pertechnetate Tc 99m Injection in the same form that is offered today by all other suppliers and which is expected by today’s nuclear pharmacist.”

Partial funding for NorthStar’s technology was provided by the U.S. Department of Energy’s National Nuclear Security Administration. Under provisions of the American Medical Isotopes Production Act of 2012, efforts have been made to establish domestic production of Mo-99 and to promote the use of Mo-99 produced without reliance on highly enriched uranium, which has been deemed a nuclear proliferation risk by Congress. NorthStar’s technology uses stable isotopes of molybdenum, rather than enriched uranium, thereby avoiding the national security and environmental risks associated with enriched uranium.

NorthStar expects to be shipping product to customers within several weeks of FDA approval.

**About the RadioGenixTM System**

The RadioGenix System is an innovative, high tech system that is approved for processing non-uranium/non highly enriched uranium molybdenum-99 (Mo-99) for the production of the important medical radioisotope, technetium-99m (Tc-99m). Prior to availability of RadioGenix technology, the U.S. supply chain for Mo-99 has been subject to frequent and sometimes severe interruptions which negatively impact patient healthcare. Approved by the U.S. Food and Drug Administration in February 2018, the RadioGenix System is the first and only on-site, automated isotope separation system of its kind for use with non-uranium/non-highly enriched uranium based Mo-99.

**Indication and Important Safety Information About the RadioGenixTM System and Sodium Pertechnetate Tc 99m Injection USP**

**INDICATION**

RadioGenix™ System is a technetium Tc-99m generator used to produce sterile, non-pyrogenic Sodium Pertechnetate Tc 99m Injection. Sodium Pertechnetate Tc-99m Injection is indicated for use in the preparation of FDA approved diagnostic radiopharmaceuticals.

Sodium Pertechnetate Tc-99m Injection is also indicated in

* Adults for: Salivary Gland Imaging and Nasolacrimal Drainage System Imaging (dacryoscintigraphy).
* Adults and pediatric patients for: Thyroid Imaging and Urinary Bladder Imaging (direct isotopic cystography) for detection of vesicoureteral reflux.

**IMPORTANT SAFETY INFORMATION**

* Radiation Exposure Risk: Sodium Pertechnetate Tc-99m injection contributes to a patient’s long-term cumulative radiation exposure. Ensure safe handling to protect patients and health care workers from unintentional radiation exposure.
* Unintended Mo-99 Exposure: Only use potassium molybdate Mo-99, processing reagents, saline and other supplies, including kits, provided by NorthStar Medical Radioisotopes. Do not administer Sodium Pertechnetate Tc-99m Injection after the 0.15microCi of Mo-99/mCi of Tc-99m limit has been reached and discard the Sodium Pertechnetate Tc-99m Injection when the 12 hour expiration time is reached; whichever occurs earlier.
* Hypersensitivity Reactions: Monitor all patients for hypersensitivity reactions.
* Adverse Reactions: Allergic reactions, including anaphylaxis, have been reported infrequently following the administration of Sodium Pertechnetate Tc 99m Injection.

To report SUSPECTED ADVERSE REACTIONS, contact NorthStar Medical Radioisotopes, LLC at 1-844-438-6659 or contact FDA at 1-800-332-1088 or [www.fda.gov/medwatch.](http://www.fda.gov/medwatch)

**Full RadioGenix prescribing information is available at:** [**www.northstarnm.com**](file:///C:\Users\lholst\Desktop\FINAL%20PR%20QA%20Website%20Handl%20Obj\www.northstarnm.com)**.**

**About Medical Radioisotopes - Molybdenum-99 (Mo-99) and Technetium-99m (Tc-99m)**

Tc-99m is a radioisotope used in a variety of diagnostic testing procedures. It is currently the most widely used medical radioisotope in the United States, used in more than 10 million diagnostic procedures annually. Tc-99m-based radiopharmaceuticals are used to diagnose and stage heart disease, cancer, infection, inflammation and other conditions.

Tc-99m is derived from the radioisotope Mo-99. The United States uses about 50% of the world’s Mo-99/Tc-99m for medical purposes, but U.S. supply of Mo-99 has been completely reliant on foreign sources and subject to frequent and sometimes protracted interruptions which negatively impact patient healthcare. Other Mo-99 producers continue to use enriched uranium in their processing which poses significant environmental concerns. NorthStar’s technology uses stable isotopes of molybdenum to produce Mo-99 domestically without incurring the concerns related to the management of toxic waste associated with Mo-99 production from enriched uranium.

**About NorthStar Medical Radioisotopes, LLC (NorthStar)**

NorthStar Medical Radioisotopes is a nuclear medicine technology company committed to providing the United States with reliable and environmentally friendly radioisotope supply solutions to meet the needs of patients and to advance clinical research. The Company’s first product is the RadioGenixTM System, an innovative and flexible platform technology initially approved by the U.S. Food and Drug Administration in February 2018 for the processing of non-uranium/non-highly enriched uranium based molybdenum-99 (Mo-99), the parent isotope of technetium-99m (Tc-99m), which is currently the most widely used diagnostic radioisotope for medical purposes. NorthStar’s proprietary and patented technologies include non-uranium based molybdenum-99 domestic production methods, patented separation chemistry systems, patented sterilization systems and a technology platform that potentially allows expanded product offerings to provide solutions in both the diagnostic and therapeutic markets. Founded in 2006 and based in Beloit, Wis., NorthStar Medical Radioisotopes, LLC is a wholly-owned subsidiary of NorthStar Medical Technologies, LLC. For more information, visit: [**www.northstarnm.com**](http://www.northstarnm.com).

**Corporate Contact:**

For NorthStar Medical Radioisotopes, LLC

Lisa Holst

Vice President Sales and Marketing

678-471-9027

[lholst@northstarnm.com](mailto:lholst@northstarnm.com)

**Media Contact:**

For NorthStar Medical Radioisotopes, LLC

Priscilla Harlan

781-799-7917

pharlan@shiningrockllc.com

# # #