# DOE and HHS Certify Sufficient $^{99}$Mo Supplies

On December 20, U.S. Secretary of Energy Jennifer M. Granholm and U.S. Secretary of Health and Human Services (HHS) Xavier Becerra jointly certified the achievement of a sufficient supply of $^{99}$Mo made without using highly enriched uranium (HEU) to meet the needs of patients in the United States. According to a press release from the agencies, this certification "paves the way for a nuclear nonproliferation milestone and supports U.S. companies by triggering a congressionally mandated ban on exports of HEU for foreign medical isotope production." HEU is a sensitive and critical product in terms of nuclear proliferation, and the Department of Energy (DOE) National Nuclear Security Administration (NNSA) works to minimize the global civilian use and availability of HEU.

"Doctors and patients across the globe can be confident that the critical medical isotope $^{99}$Mo will be there when they need it, and we can provide that assurance without making any further exports of HEU," said Granholm. "Today's certification is another example of DOE's world-leading expertise creating win–win outcomes that make the world safer while advancing jobs, improving health care, and increasing the quality of life here at home."

$^{99}$Mo is used in more than 40,000 medical diagnostic procedures in the United States each day. For decades, the United States had no capability for domestic production of the isotope. To ensure a stable supply, HEU was exported to foreign medical isotope producers that used the material to produce $^{99}$Mo for the U.S. and global markets.

Achieving a sufficient supply of $^{99}$Mo produced without the use of HEU is the result of significant accomplishments by DOE, HHS, and the commercial $^{99}$Mo industry. The DOE NNSA has provided financial and technical assistance to help global $^{99}$Mo producers convert from HEU to low-enriched uranium (LEU). DOE/NNSA has also supported development of a domestic production capability for non-HEU $^{99}$Mo by awarding more than $200 million in cost-shared cooperative agreements with commercial entities, providing technical support from the U.S. National Laboratories, and establishing a Uranium Lease and Take-Back Program for industry.

HHS's role in achieving this milestone included approvals for use of $^{99}$Mo produced by global suppliers using LEU and the 2018 FDA approval of the New Drug Application for the $^{99}$Mo production system of NorthStar Medical Radioisotopes, one of NNSA's commercial partners. Both the DOE and HHS noted that they will continue to work together and with commercial entities to further bolster the U.S. supply of non-HEU $^{99}$Mo.

"With more than 80% of diagnostic imaging in the U.S. relying on nuclear medicine isotopes like $^{99}$Mo, the FDA has a key role to play to ensure a sufficient supply is available for critical daily medical procedures," said Acting FDA Commissioner Janet Woodcock, MD. "We're pleased to partner with DOE and other federal partners to contribute to this important achievement."

*U.S. Department of Energy*
*U.S. Department of Health and Human Services*

# FDA Approves New $^{68}$Ga Kit for Prostate Cancer PET

Telix Pharmaceuticals (Melbourne, Australia; Indianapolis, IN) announced on December 20 that the U.S. Food and Drug Administration (FDA) had approved Illucix (TLX591-CDx), the company's kit for preparation of $^{68}$Ga-gozetotide ($^{68}$Ga–prostate-specific membrane antigen [PSMA]-11). The product is approved for PET imaging in patients with prostate cancer with suspected metastasis who are candidates for initial definitive therapy or in whom recurrence is suspected based on elevated serum prostate-specific antigen levels.

The FDA first approved $^{68}$Ga-PSMA-11 PET for prostate cancer imaging in December 2020, but access was available only through the University of California Los Angeles and the University of California San Francisco. "The approval of Illucix will give patients considerably improved access to PSMA PET imaging, an advanced diagnostic tool that was recently included in the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology for Prostate Cancer," said A. Oliver Sartor, MD, Medical Director of the Tulane Cancer Center (New Orleans, LA). "With patient doses able to be prepared onsite or via commercial radiopharmacy networks, either via generator or cyclotron, Illucix delivers flexible patient scheduling and on-demand access throughout the day."

According to a Telix press release issued on December 20, Illucix can be prepared with $^{68}$Ga via either GE's FASTlab cyclotrons or in nuclear pharmacies and health care centers using the Eckert and Ziegler GalliaPharm generator or the IRE ELiT Galli Eo generator. Along with a 4-hour shelf life after radiolabeling, these generation options will allow expansion of PSMA PET in prostate cancer. "This product offers a level of flexibility and accessibility to health care professionals we really haven't seen before in this class of products and may help us provide better patient experiences as a result," said Dr. Sartor. With a distribution network encompassing more than 140 nuclear pharmacies through an agreement with Cardinal Health and PharmaLogic, Telix noted that Illucix will be available to more than 85% of eligible PET imaging sites in the United States.

*Telix Pharmaceuticals*