

## Estrogen Receptor Agent Approved

PETNET Solutions, Inc. (a part of Siemens Medical Solutions USA, Inc.; Malvern, PA), and Zionexa USA (New York, NY) announced on May 27 U.S. Food and Drug Administration (FDA) approval of the Cerianna (fluoroestradiol F 18) injection for intravenous use. Cerianna is a molecular imaging agent indicated for use in PET imaging for detection of estrogen receptor–positive lesions as an adjunct to biopsy in patients with recurrent or metastatic breast cancer. It is the first <sup>18</sup>F-labeled PET agent specifically indicated for use in patients with recurrent or metastatic breast cancer. Cerianna will be commercially available beginning in late 2020/early 2021 through PETNET Solutions, Inc., Zionexa USA's manufacturer and exclusive commercial distributor in the United States. Additional manufacturing sites will be added as each receives regulatory approval to begin manufacturing. "Cerianna (fluoroestradiol F 18) will provide clinicians with additional, previously unavailable data on the estrogen receptor status of tumors across the patient's entire body, providing additional data to enhance therapeutic decision making," said Peter Webner, chief executive officer of Zionexa USA. The 2 companies announced on December 5, 2019, that they had entered into an exclusive agreement for the manufacture and distribution of the agent, pending FDA approval.

*PETNET Solutions, Inc.  
Zionexa USA*

## Hospital Reporting of Radionuclide Infiltrations

On May 18, David Townsend, PhD, a co-inventor of PET/CT and a pioneer in 3D reconstruction algorithms for hybrid imaging, wrote on the *STAT* news site about appropriate hospital reporting of radioisotope injection infiltration. In addition to explaining for non-medical readers how infiltrations occur and the potential effects, both in incorrect image assessment and unintentional tissue

dose, Townsend reviewed the history of associated reporting requirements. The Nuclear Regulatory Commission (NRC) first required hospitals to report isotope "misadministration" in 1980, changing that term to "medical event" in 2002 and establishing risk-based reporting limits of 500-mSv tissue exposure. However, the NRC specifically exempts hospitals from reporting infiltrations, even when these exceed the designated threshold of 500-mSv exposure. Townsend pointed to this "loophole" as contributing to a situation in which reporting requirements are inconsistent—radioactive isotopes spilled and exposing tissue to >500 mSv trigger the reporting requirement, whereas internal infiltration of the same or higher amounts does not. The result, he stated, "is that the NRC—along with patients and physicians—have no idea of the true impact of infiltrations." He cited the increasingly important role of radioisotope-based theranostics as a compelling reason for readdressing this inconsistency. He noted that the NRC is now re-evaluating the reporting requirement. He concluded by stating that "as with all other medical events, if an infiltration exceeds the reporting threshold, it should be reported. This will drive quality improvements and improve patient care and safety." The complete perspective article is available at: <https://www.statnews.com/2020/05/18/hospitals-shouldnt-be-exempt-from-reporting-radioisotope-infiltrations/>.

*STAT*

## Retevmo Approved in Lung and Thyroid Cancers

On May 8, the U.S. Food and Drug Administration (FDA) announced the approval of Retevmo (selpercatinib) capsules to treat 3 types of tumors: non–small cell lung cancer (NSCLC), medullary thyroid cancer (MTC), and other types of thyroid cancers in patients whose tumors have an alteration (mutation or fusion) in a specific gene (RET or "rearranged during transfection"). Retevmo, from Loxo Oncology

(Stamford, CT; a subsidiary of Eli Lilly), is the first therapy approved specifically for cancer patients with RET gene alterations. "Innovations in gene-specific therapies continue to advance the practice of medicine at a rapid pace and offer options to patients who previously had few," said Richard Pazdur, MD, director of the FDA Oncology Center of Excellence and acting director of the Office of Oncologic Diseases in the FDA Center for Drug Evaluation and Research. "The FDA is committed to reviewing treatments like Retevmo that are targeted to specific subsets of patients with cancer."

The specific settings in which Retevmo was approved include: NSCLC that has spread in adults; advanced MTC or MTC that has spread in patients 12 y and older who require systemic therapy; and advanced RET fusion-positive thyroid cancer in those age 12 y and older that requires systemic therapy and has stopped responding to radioactive iodine or is not appropriate for radioactive iodine therapy. Retevmo is a kinase inhibitor, and administration of the agent requires laboratory testing to select for the RET gene alteration. For the radioactive iodine–refractory or –inappropriate group, efficacy studies were conducted in 19 radioactive iodine–refractory patients with RET fusion-positive thyroid cancer who had received another prior systemic treatment and 8 who had not received any additional therapy other than radioactive iodine treatment. The overall response rate for the 19 previously treated patients was 79%. For 87% of these patients who saw a response to the treatment, this response lasted at least 6 mo. Overall response for the remaining 8 patients was 100%, with 6 patients seeing a response to the treatment and responses lasting at least 6 mo. Retevmo was approved under the Accelerated Approval pathway, which addresses drugs that treat serious or life-threatening diseases and generally provide a meaningful advantage over existing treatments. In addition, Retevmo received Orphan Drug

designation, which provides incentives to assist and encourage the development of drugs for rare diseases.

*U.S. Food and Drug Administration*

### **NRC and Regulatory Relief During COVID-19**

In a teleconference held on April 30, the Nuclear Regulatory Commission (NRC) Advisory Committee on the Medical Uses of Isotopes (ACMUI) met with NRC staff to review and discuss the ACMUI COVID-19 Subcommittee's draft recommendations for regulatory relief measures for medical licensees during the COVID-19 public health emergency. In its report, the subcommittee provided several recommendations in specific areas in which licensees may be unable to meet regulatory requirements in a timely manner because of the public health emergency. The full ACMUI endorsed the draft,

which covered the following general areas: (1) training and education; (2) regulatory reporting; (3) medical event reporting; (4) radiation protection activities; (5) physical presence; (6) inspections; and (7) regulatory fees. As part of the discussion, ACMUI members cited hypothetical scenarios in which a facility's authorized user (AU) or authorized medical physicist (AMP) could not be physically present for treatment because of suspected or confirmed COVID-19 infection. The ACMUI concluded that there should be no change to the physical presence requirements for high-dose-rate brachytherapy or gamma knife stereotactic radiosurgery because these are high-risk procedures that require the physical presence of the AU and AMP. In addition, the ACMUI discussed and considered concerns about the possibility of regulatory relief for

patient release criteria after radionuclide therapy during the pandemic. The ACMUI agreed that for exceptional situations related to patient release during COVID-19, medical licensees should contact the NRC or their regional regulatory office to seek temporary exemptions on a case-by-case basis. NRC staff will consider the ACMUI recommendations when developing guidance for medical licensees that request temporary exemptions during the pandemic. Full transcripts and handouts from the ACMUI meeting are available at: <https://www.nrc.gov/reading-rm/doc-collections/acmui/meetings/2020.html>. The ACMUI COVID-19 Subcommittee report is available under ACMUI Subcommittee Reports at: <https://www.nrc.gov/reading-rm/doc-collections/acmui/reports/>.

*Nuclear Regulatory Commission*