GE HealthCare Announces FES PET Imaging Recommendation in NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)

May 24, 2023

- NCCN Guidelines® for clinicians and patients now recommend the use of FES PET for ER+ positive disease under certain circumstances during the systemic staging workup of patients with recurrent or metastatic breast cancer (MBC).
- Cerianna (fluoroestradiol F18) injection is the first and only U.S. Food and Drug Administration (FDA) approved imaging agent helping clinicians assess estrogen receptor-positive (ER+) lesion status to potentially aid in better informing clinical decisions and improving patient outcomes.
- In March 2023, Appropriate Use Criteria (AUC) for ER-targeted PET imaging was also published by the Society of Nuclear Medicine and Molecular Imaging (SNMMI)[1].

MARLBOROUGH, Mass.--(BUSINESS WIRE)--May 24, 2023-- GE HealthCare, a leader in breast cancer care technology and diagnostics, has today announced that NCCN Guidelines® for clinicians and patients now recommend the use of FES PET for ER+ positive disease under certain circumstances during the systemic staging workup of patients with recurrent or metastatic breast cancer. GE HealthCare's Cerianna, available in the U.S., is the only FDA approved FES PET imaging agent. This inclusion in the NCCN Guidelines comes after the Society of Nuclear Medicine and Molecular Imaging (SNMMI) recently published Appropriate Use Criteria to guide referring and imaging physicians in appropriate use of estrogen receptor (ER)-targeted PET imaging with 16α-^{18}F-fluoro-17ß Fluoroestradiol.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20230524005415/en/

FES PET is now included in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) (Graphic: Business Wire)

In the U.S., it is estimated that 181,000[2] people have metastatic breast cancer (also called stage 4)[3], with a five-year survival rate of 28 percent[4]. Currently, when treating metastatic breast cancer patients, oncologists base clinical decisions on diagnostic tools including biopsy results which only represent the sampled area of the tumor. However, ER expression – one of the most common breast cancer biomarkers - can vary both within the primary tumor, across different lesions[5], and change over time.

Cerianna is indicated for use with PET imaging for the detection of ER+ lesions as an adjunct to biopsy in patients with recurrent or metastatic breast cancer. Providing a whole-body view of ER+ lesions, Cerianna may deliver a comprehensive assessment to assist in making an informed diagnosis and treatment plan for the patient. This could potentially enable more targeted and individualized treatment strategy and avoid the selection of inappropriate or less effective therapies.

"The latest NCCN Guidelines reflect the impact the Cerianna PET is starting to have in the care of patients with metastatic breast cancer," Dr. David Mankoff, Professor and Vice Chair of Research in radiology at University of Pennsylvania, commented. "As was the case for fluorodeoxyglucose (FDG) PET, inclusion in the NCCN guidelines will help support access for Cerianna PET for patients with MBC and provides impetus for the medical community to define the clinical scenarios where Cerianna PET will be most helpful."

"FES PET, like FDG PET, is now included in the NCCN Guidelines. We have an opportunity to use FES PET to assess ER function in all tumor sites in patients with ER+ metastatic breast cancer," Dr. Hannah M Linden, Breast Medical Oncologist, University of Washington and Fred Hutchinson Cancer Center in Seattle, Washington, said. "This is a helpful tool for diagnostic confirmation and may have the ability to aid in prognosis and prediction of clinical benefit from endocrine based therapies, including with CDK 4/6 inhibitors. We have many endocrine options now, and FES PET may identify patients who remain ER+ and thus potentially benefit from endocrine based therapy."

"We are delighted to see the inclusion of Cerianna PET in the NCCN breast oncology guidelines, for potential use when oncologists are evaluating metastatic breast cancer patients," Dr. Mark Hibberd, Chief Medical Officer at GE HealthCare's Pharmaceutical Diagnostics segment, said. "Detecting ER+ lesions in patients with recurrent or metastatic breast cancer could potentially aid oncologists, surgeons and clinicians in choosing the most appropriate therapy for patients."

The NCCN is a not-for-profit alliance of 33 leading U.S. cancer centers devoted to patient care, research, and education. The NCCN Guidelines are the recognized standard for clinical direction and policy in cancer care and are the most thorough and frequently updated clinical practice guidelines available in any area of medicine.

GE HealthCare's Pharmaceutical Diagnostics segment is a global leader in imaging agents used to support around 100 million procedures per year globally, equivalent to three patient procedures every second. Its Molecular Imaging portfolio combines established proprietary products across cardiology, neurology and oncology, with an innovative pipeline, all aimed at enabling better informed diagnosis and monitoring for improved therapy decision making and clinical outcomes.

NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

About GE HealthCare Technologies Inc.
GE HealthCare is a leading global medical technology, pharmaceutical diagnostics, and digital solutions innovator, dedicated to providing integrated solutions, services, and data analytics to make hospitals more efficient, clinicians more effective, therapies more precise, and patients healthier and happier. Serving patients and providers for more than 100 years, GE HealthCare is advancing personalized, connected, and compassionate care, while simplifying the patient's journey across the care pathway. Together our Imaging, Ultrasound, Patient Care Solutions, and Pharmaceutical Diagnostics businesses help improve patient care from diagnosis, to therapy, to monitoring. We are an $18.3 billion business with 50,000 employees working to create a world where healthcare has no limits.

Follow us on Facebook, LinkedIn, Twitter, and Insights for the latest news, or visit our website https://www.gehealthcare.com/ for more information.

INDICATIONS AND USAGE:
CERIANNA is indicated for use with positron emission tomography (PET) imaging for the detection of estrogen receptor (ER)-positive lesions as an adjunct to biopsy in patients with recurrent or metastatic breast cancer.

Limitations of Use:
Tissue biopsy should be used to confirm recurrence of breast cancer and to verify ER status by pathology. CERIANNA is not useful for imaging other receptors, such as human epidermal growth factor receptor 2 (HER2) and the progesterone receptor (PR).

Important Safety Information
CONTRAINDICATIONS

- None.

WARNINGS AND PRECAUTIONS
Risk of Misdiagnosis
Inadequate Tumor Characterization and Other ER-Positive Pathology

- Breast cancer may be heterogeneous within patients and across time. CERIANNA images ER and is not useful for imaging other receptors such as HER2 and PR. The uptake of fluoroestradiol F 18 is not specific for breast cancer and may occur in a variety of ER-positive tumors that arise outside of the breast, including from the uterus and ovaries. Do not use CERIANNA in lieu of biopsy when biopsy is indicated in patients with recurrent or metastatic breast cancer.

False Negative CERIANNA Scan

- A negative CERIANNA scan does not rule out ER-positive breast cancer. Pathology or clinical characteristics that suggest a patient may benefit from systemic hormone therapy should take precedence over a discordant negative CERIANNA scan.

Radiation Risks

- Diagnostic radiopharmaceuticals, including CERIANNA, expose patients to radiation. Radiation exposure is associated with a dose-dependent increased risk of cancer. Ensure safe drug handling and patient preparation procedures (including adequate hydration and voiding) to protect patients and health care providers from unintentional radiation exposure.

Pregnancy Status

- Assessment of pregnancy status is recommended in females of reproductive potential before administering CERIANNA.

ADVERSE REACTIONS

- In Clinical Trials (n=1207) the most common adverse reactions seen occurred at a rate < 1%: were injection-site pain and dysgeusia.

USE IN SPECIFIC POPULATIONS
Pregnancy
Risk Summary

- All radiopharmaceuticals, including CERIANNA, have the potential to cause fetal harm depending on the fetal stage of development and the magnitude of radiation dose. Advise a pregnant woman of the potential risks of fetal exposure to radiation from administration of CERIANNA.
- There are no available data on CERIANNA use in pregnant women. No animal reproduction studies using fluoroestradiol F 18 have been conducted to evaluate its effect on female reproduction and embryo-fetal development.
- The estimated background risk of major birth defects and miscarriage for the indicated populations is unknown. All pregnancies have a background risk of birth defects, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Lactation
Risk Summary

- There are no data on the presence of fluoroestradiol F 18 in human milk, or its effects on the breastfed infant or milk production. Lactation studies have not been conducted in animals. Advise a lactating woman to avoid breastfeeding for 4 hours after CERIANNA administration in order to minimize radiation exposure to a breastfed infant.

Pediatric Use

- The safety and effectiveness of CERIANNA in pediatric patients have not been established.

Geriatric Use

- Clinical studies of fluoroestradiol F 18 injection did not reveal any difference in pharmacokinetics or biodistribution in patients aged 65 and over.

DRUG INTERACTIONS
Systemic Endocrine Therapies that Target Estrogen Receptors

- Certain classes of systemic endocrine therapies, including ER modulators and ER down-regulators, block ER, reduce the uptake of fluoroestradiol F 18, and may reduce detection of ER-positive lesions after administration of CERIANNA. Drugs from these classes such as tamoxifen and fulvestrant may block ER for up to 8 and 28 weeks, respectively. Do not delay indicated therapy in order to administer CERIANNA. Administer CERIANNA prior to starting systemic endocrine therapies that block ER.

To report SUSPECTED ADVERSE REACTIONS, contact Zionexa US Corp, a GE Healthcare Company at +1.800.654.0118 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

[1] J Nucl Med 2023 Mar;64(3):351-354. doi: 10.2967/jnumed.123.265420

[2] Gogate A, et al. Projecting the Prevalence and Costs of Metastatic Breast Cancer From 2015 through 2030. JNCI Cancer Spectrum. August 2021

[3] Mariotto et al, 2017

[4] https://www.cancer.org/cancer/breast-cancer/understanding-a-breast-cancer-diagnosis/breast-cancer-survival-rates.html

[5] Kurland, et al. Between-patient and within-patient (site-to-site) variability in estrogen receptor binding, measured in vivo by 18F-fluoroestradiol PET. J Nucl Med. 2011;52(10):1541-1549 / Currin, et al. Temporal Heterogeneity of Estrogen Receptor Expression in Bone-Dominant Breast Cancer: 18F-Fluoroestradiol PET Imaging Shows Return of ER Expression. J Natl Compr Canc Netw. 2016;14(2):144-147

View source version on businesswire.com: https://www.businesswire.com/news/home/20230524005415/en/

GE HealthCare Media Contact:
Mathilde Bouscaillou
M +33 647 008 271
Mathilde.Bouscaillou@ge.com

Source: GE HealthCare