GE HealthCare Pharmaco-Economic Study Demonstrates Adding Breast Oncology PET Tracer to Standard Workup of Patients with Metastatic or Recurrent Breast Cancer May Yield Beneficial Clinical and Economic Outcomes, Potentially Saving $142M Over Five...

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- Adding a PET/CT scan with [^{18}F]FES, a breast oncology PET tracer, may increase the accuracy of knowing the estrogen receptor (ER) status. This is notable when a tumor sample cannot be obtained, or the risk of a biopsy-related complication is high.
- Increased diagnostic accuracy may help clinicians select more effective treatments and decrease the rate of re-biopsies, resulting in the potential cost savings of $142M to the US healthcare system over a five-year period,[1] according to a new study published in PLOS ONE.
- The study shows that adding a PET/CT scan with the [^{18}F]FES tracer, commercially available in the US as Cerianna, to biopsy/immunohistochemistry (IHC) may increase the number of true positive and true negative ER status test results by up to eight percentage points[2] compared to when biopsy/IHC is used alone.

MARLBOROUGH, Mass.--(BUSINESS WIRE)--Jun. 4, 2024--

GE HealthCare Pharmaco-Economic Study Demonstrates Adding Breast Oncology PET Tracer to Standard Workup of Patients with Metastatic or Recurrent Breast Cancer May Yield Beneficial Clinical and Economic Outcomes, Potentially Saving $142M Over Five Years in the US

In a GE HealthCare sponsored pharmaco-economic study published in peer-reviewed journal PLOS ONE, the incidence, prevalence, diagnostic pathways, and treatments of different patients with metastatic or recurrent breast cancer were analyzed using a combination of widely accepted statistical modelling methods to estimate the clinical and associated economic impact of adding a PET/CT scan with [^{18}F]FES, a breast oncology PET tracer, to the current standard diagnostic process.

Breast cancer is the most diagnosed cancer worldwide, with approximately 2.3 million new cases appearing in 2020 alone.[3] Correct identification of the receptor status in breast cancer is crucial to optimize treatment; however, the diagnostic standard of care which involves biopsy/IHC and imaging, can yield inconclusive results. [^{18}F]FES can be a powerful tool, providing high diagnostic accuracy in detection of estrogen receptor (ER)-positive lesions. The study demonstrated that adding a PET/CT scan with [^{18}F]FES to biopsy/IHC may increase the diagnostic accuracy of the ER status in all appropriate patients with metastatic or recurrent breast cancer. The clinical and economic benefits were especially pronounced in those situations where a tumor sample cannot be obtained, or the risk of a biopsy-related complication is high.

Regina Young, Head of Global Market Access in the Pharmaceutical Diagnostics segment of GE HealthCare and lead author of the study said, “We found that if [^{18}F]FES PET/CT was added to the standard diagnostic work up and in line with the Appropriate Use Criteria (AUC) for ER-targeted PET Imaging,[4] the increase in diagnostic accuracy could improve the clinical outcomes. Additionally, results suggested a positive correlation between increased diagnostic accuracy, especially when multiple lesions are present,” said Young. "The increase in true ER-positive and ER-negative results may have beneficial clinical and economic outcomes primarily driven by the avoidance of repeated biopsies and futile treatments.”

In 2023, FES PET imaging was added to the National Cancer Care Network (NCCN) Clinical Practice Guidelines in Oncology for ER-positive disease under certain circumstances during the systemic staging workup of patients with metastatic and recurrent breast cancer. This inclusion came after the Society of Nuclear Medicine and Molecular Imaging (SNMMI) published its AUC to guide referring and imaging physicians in appropriate use of ER-targeted PET imaging with 16α-^{18}F-fluoro-17ß Fluoroestradiol. According to SNMMI, the inclusion of FES PET in its AUC is intended to help healthcare practitioners provide patients with the best care in a cost-effective manner. The AUC may also enable more efficient approval of FES use by payers.[5]

GE HealthCare’s Cerianna is the only FDA-approved FES PET imaging agent. Cerianna is indicated for use with PET imaging for the detection of ER-positive lesions as an adjunct to biopsy in patients with metastatic and recurrent breast cancer. Providing a whole-body view of ER-positive lesions, Cerianna may deliver a comprehensive assessment to assist in making an informed diagnosis and individualized treatment plan for the patient.

GE HealthCare’s Pharmaceutical Diagnostics segment is a global leader in imaging agents used to support around 119 million procedures per year globally, equivalent to four 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.

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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

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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 Bind to ER

- Drugs that bind to the ER, including SERMs and SERDs, may compete with the binding of fluoroestradiol F18 and may reduce detection of ER-positive lesions with CERIANNA.
- Before administration of CERIANNA, discontinue drugs that bind to the ER, such as SERMs and SERDs, for at least 5 biological half-lives: (e.g. elacestrant for 11 days, tamoxifen for 8 weeks and fulvestrant for 28 weeks).

To report SUSPECTED ADVERSE REACTIONS, contact GE HealthCare at 800 654 0118 (option 2 then option 1) or by email at GPV.drugsafety@gehealthcare.com or FDA at 800 FDA 1088 or www.fda.gov/medwatch

[1] Munter-Young R, Fuentes-Alburo A, DiGregorio N, Neeser K, Gultyaev D (2024) Clinical and economic outcomes of adding [18F]FES PET/CT in estrogen receptor status identification in metastatic and recurrent breast cancer in the US. PLoS ONE 19(5): e0302486. https://doi.org/10.1371/journal.pone.0302486

[2] Munter-Young, Fuentes-Alburo, DiGregorio, Neeser, Gultyaev, 2024, Table 3

[3] Sung H, Ferlay J, Siegel RL, Laversanne M, Soerjomataram I, Jemal A, et al. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. CA Cancer J Clin. 2021;71(3):209–49. Epub 20210204. pmid:33538338.

[4] Ulaner G, Mankoff D, Clark AS, Fowler AM, Linden HM, Peterson LM, Dehdashti F, Kurland BF, Mortimer J, Mouabbi J, Hyuk Moon D, de Vries EGE (2023) Summary: Appropriate Use Criteria for Estrogen Receptor-Targeted PET Imaging with 16α-F-Fluoro-17β-Fluoroestradiol. The Journal of Nuclear Medicine 64 (3) 351-354.
https://doi.org/10.2967/jnumed.123.265420

[5] Ulaner G, Mankoff D, Clark AS, Fowler AM, Linden HM, Peterson LM, Dehdashti F, Kurland BF, Mortimer J, Mouabbi J, Hyuk Moon D, de Vries EGE (2023) Summary: Appropriate Use Criteria for Estrogen Receptor-Targeted PET Imaging with 16α-F-Fluoro-17β-Fluoroestradiol. The Journal of Nuclear Medicine 64 (3) 351-354.
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