Zionexa US Corp. secures pass-through payment status and assignment of C-code for Cerianna™

Indianapolis, IN, October 2, 2020 – Zionexa US Corp., a wholly owned subsidiary of Zionexa SAS, specialized in the development and commercialization of in-vivo biomarkers for use in guiding targeted therapies in oncology, announced that the Center for Medicare and Medicaid Services (CMS) has approved transitional pass-through status and reimbursement through a C-code for Cerianna (fluoroestradiol F-18) injection.

Cerianna (fluoroestradiol F-18) injection is a new molecular imaging agent approved by the Food and Drug Administration (FDA) indicated for use in positron emission tomography (PET) imaging for the detection of estrogen receptor-positive lesions as an adjunct to biopsy in patients with recurrent or metastatic breast cancer (MBC). Cerianna (fluoroestradiol F-18) is the first FDA-approved F-18 PET imaging agent specifically indicated for use in patients with recurrent or metastatic breast cancer. The temporary code, C9060, is effective since October 1, 2020. The permanent code will be expected in January 2021.

"*Receiving the pass-through status and the C-code for Cerianna is a very important step in our process to get our new molecule commercialized in the United-States and provide physicians access to a non-invasive and qualitative way to find the optimal treatment for the patient with MBC. MBC is a real health issue with more than 40,000 MBC-related deaths expected in the U.S. in 2019,*" said Peter Webner, CEO of Zionexa USA. "*Our team continues to organize and optimize on our commercial and production strategy and we expect a launch at the end of 2020."*

About Metastatic Breast Cancer

Metastatic breast cancer is the most advanced stage of breast cancer. Also called stage IV or advanced breast cancer, MBC means that the cancer has spread beyond the breast to other parts of the body. MBC affects more than 168,000[1] patients in the United-States.

[1] Mariotto *et al*, 2017

About Zionexa

Zionexa is an international and innovative company developing and commercializing in-vivo biomarkers for guiding targeted therapies in oncology, to improve patients' pathway and provide them a better quality of life.

For more information, please visit www.zionexa.com

About Cerianna

Cerianna (fluoroestradiol F-18) is a new molecular imaging agent approved by the Food and Drug Administration (FDA) indicated for use in positron emission tomography (PET) imaging for the detection of estrogen receptor-positive lesions as an adjunct to biopsy in patients with recurrent or metastatic breast cancer. Cerianna (fluoroestradiol F-18) is the first FDA-approved F-18 PET imaging agent specifically indicated for use in patients with recurrent or metastatic breast cancer.

For more information about Cerianna, please visit www.cerianna.com (accessible only for US HCPs)

INDICATION

Cerianna is a radioactive diagnostic agent 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

Adverse Reactions – Reported adverse reactions include: injection site pain and dysgeusia.

Radiation Risks – Ensure safe drug handling and patient preparation procedures to protect patients and health care providers from unintentional radiation exposure.

Risk of Misdiagnosis – Do not use CERIANNA in lieu of biopsy when biopsy is indicated in patients with recurrent or metastatic breast cancer.

Contraindications – None.

Use in Specific Populations – Lactation: Interrupt breastfeeding.

Advise a lactating woman to avoid breastfeeding for 4 hours after CERIANNA administration.

To report SUSPECTED ADVERSE REACTIONS, contact Zionexa US Corp at +1.844.946.6392 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

· Recommended dose is 222 MBq (6 mCi), with a range of 111 MBq to 222 MBq (3 mCi to 6 mCi), administered as an intravenous injection over 1 to 2 minutes.

· Recommended imaging start time is 80 minutes (range 20 minutes to 80 minutes) after drug administration.

· See full prescribing information for additional preparation, administration, imaging, and radiation dosimetry information.

DOSAGE FORMS AND STRENGTHS

Injection: 148 MBq/mL to 3,700 MBq/mL (4 mCi/mL to 100 mCi/mL) of fluoroestradiol F-18 in a multiple-dose vial.

DRUG INTERACTIONS

· Drugs such as tamoxifen and fulvestrant that block the estrogen receptor reduce the uptake of fluoroestradiol F-18. Do not delay indicated therapy in order to administer Cerianna. Image patients with Cerianna prior to starting systemic endocrine therapies that block ER.

You can find the full prescribing information here: https://www.zionexa.com/wp-content/uploads/2020/05/cerianna-prescribing-information.pdf

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