First Cerianna™ doses distributed in San Francisco area

Indianapolis, IN, December 9, 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 first Cerianna (Fluroroestradiol F-18) doses have been distributed to two oncology imaging centers in the San Francisco area. These two doses of Cerianna represent the future for two breast cancer patients to be able to receive PET scans that will have a more direct impact on the course of their therapy, and overall provide them with more informed and better care.

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 biomarker specifically indicated for use in patients with recurrent or metastatic breast cancer. The permanent HCPCS code, A9591 "Fluoroestradiol F 18, diagnostic, 1 millicurie" will be effective January 2021.

"This is a momentous day: our international team worked everyday since the creation of Zionexa to achieve this tremendous milestone. Our mission is to continue this impressive work in order to help improve patient's quality of life and guiding therapies. Cerianna can help guide therapies for recurrent and MBC patients and our ambition is to provide all patients who have the need for it in the United States," said Peter Webner, CEO of Zionexa US Corp. *"Cerianna is already being produced and distributed in San Francisco and we expect to extend to Los Angeles, New York, Philadelphia, Raleigh Durham and Jacksonville next month."*

"Siemens' Healthineers PETNET Solutions is pleased to be the exclusive commercial US manufacturer and distributor of Cerianna" says Barry Scott, Head of PETNET Solutions. *"The ability to be able to deliver Cerianna and help provide answers for these patients is a key milestone. Furthermore, PETNET is providing solutions that address society's most challenging diseases, like breast cancer. Our continued investment in our network will enable us to extend access to a greater population in the coming months."*

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.

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

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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.

[1] Mariotto *et al*, 2017

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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