Press

Joint Press Release

by PETNET Solutions, Inc., and Zionexa USA

Malvern, Pa., and New York, N.Y.

May 27, 2020

PETNET Solutions and Zionexa USA Announce FDA Approval of Cerianna (fluoroestradiol F 18)

- **New radiopharmaceutical intended for PET imaging of metastatic breast cancer patients**
- **Commercial availability slated for late 2020/early 2021**
- **PETNET Solutions, Inc., is exclusive U.S. commercial supplier**

PETNET Solutions, Inc., a Siemens Healthineers company, and Zionexa USA, a wholly owned subsidiary of Zionexa SAS, have announced that the Food and Drug Administration (FDA) has approved Cerianna™ (fluoroestradiol F 18) injection for intravenous use. Cerianna (fluoroestradiol F 18) is a molecular imaging agent 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.

Cerianna (fluoroestradiol F 18) will be commercially available beginning in late 2020/early 2021 through PETNET Solutions, Inc., Zionexa USA's manufacturer and exclusive commercial distributor in the U.S. Additional manufacturing sites will be added as each site receives regulatory approval to commence manufacturing.

"PETNET Solutions, Inc., is proud to work with Zionexa USA as the exclusive U.S. commercial supplier making Cerianna (fluoroestradiol F 18) accessible to imaging centers and their breast

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cancer patients," said Barry Scott, Head of PETNET Solutions, Inc. "Our extensive network of radiopharmacies enables us to increase access to cutting-edge radiotracers such as Cerianna (fluoroestradiol F 18), helping healthcare facilities address the challenge of recurrent and metastatic breast cancer."

"Zionexa is pleased to be able to make Cerianna (fluoroestradiol F 18) commercially available through the extensive manufacturing network of PETNET Solutions, Inc.," said Peter Webner, Chief Executive Officer of Zionexa USA. "PETNET has been a great partner to Zionexa and has surpassed our expectations as a contract manufacturer. 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."

For further information on Cerianna (fluoroestradiol F 18), please see www.zionexa.com

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Siemens Healthineers AG (listed in Frankfurt, Germany: SHL) is shaping the future of Healthcare. As a leading medical technology company headquartered in Erlangen, Germany, Siemens Healthineers enables healthcare providers' worldwide through its regional companies to increase value by empowering them on their journey towards expanding precision medicine, transforming care delivery, improving the patient experience, and digitalizing healthcare. Siemens Healthineers is continuously developing its product and service portfolio, with AI-supported applications and digital offerings that play an increasingly important role in the next generation of medical technology. These new applications will enhance the company's foundation in in-vitro diagnostic, image-guided therapy, and in-vivo diagnostics. Siemens Healthineers also provides a range of services and solutions to enhance the healthcare provider's ability to provide high-quality, efficient care to patients. In fiscal 2019, which ended on September 30, 2019, Siemens Healthineers, which has approximately 52,000 employees worldwide, generated revenue of €14.5 billion and adjusted profit of €2.5 billion.
Further information is available at www.siemens-healthineers.com.

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.

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.

IMPORTANT SAFETY INFORMATION

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.

ADVERSE REACTIONS
Reported adverse reactions include: injection-site pain and dysgeusia
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.

CONTRAINDICATIONS · None.

WARNINGS AND PRECAUTIONS

· Risk of Misdiagnosis. Do not use CERIANNA in lieu of biopsy when biopsy is indicated in patients with recurrent or metastatic 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. Ensure safe drug handling and patient preparation procedures to protect patients and health care providers from unintentional radiation exposure.

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.

USE IN SPECIFIC POPULATIONS
· Lactation: Interrupt breastfeeding. Advise a lactating woman to avoid breastfeeding for 4 hours after CERIANNA administration

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).

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