GE Healthcare Acquires Zionexa; Molecular Imaging Agent Aims to Enable More Targeted Treatment for Metastatic Breast Cancer Patients

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- *GE Healthcare to scale Zionexa's FDA-approved PET imaging agent, Cerianna (fluoroestradiol F-18), used as an adjunct to biopsy for the detection of estrogen receptor (ER) positive lesions to help inform treatment selection for patients with recurrent or metastatic breast cancer*
- *Aims to make Cerianna available to 75% of metastatic breast cancer patients in the U.S. by 2023*
- *Acquisition demonstrates GE Healthcare's commitment to its precision health vision and builds additional pipeline of oncology and neurology tracers to help physicians personalize treatment*

Marlborough, MA, U.S. – 6 May 2021 – GE Healthcare today announced the acquisition of Zionexa, a leading innovator of in-vivo oncology and neurology biomarkers that help enable more personalized healthcare. The company aims to develop and bring to market Zionexa's pipeline biomarkers, as well as the recently FDA-approved PET imaging agent, Cerianna™ (fluoroestradiol F-18), which is used as an adjunct to biopsy for the detection of estrogen receptor (ER) positive lesions to help inform treatment selection for patients with recurrent or metastatic breast cancer.

It is estimated that 168,000 people have metastatic breast cancer ("Stage 4") in the U.S. [1], with a five-year survival rate of 28 percent[2]. Cerianna has been commercially available in the U.S. since December 2020 and today is accessible to approximately 25 percent of the relevant patient population. By leveraging its Molecular Imaging Supply Chain, R&D, Medical Affairs, Market Access, Regulatory, Quality and Commercial expertise, GE Healthcare's Pharmaceutical Diagnostics business - the global leader in pharmaceutical imaging agents - aims to scale Cerianna to be accessible to a minimum of 75 percent of patients by 2023.

Kevin O'Neill, President and CEO of GE Healthcare Pharmaceutical Diagnostics, said: "Like GE Healthcare, Zionexa's products are aimed at enabling more precise diagnosis, improved treatment decision-making and ultimately better clinical outcomes for patients. This acquisition further demonstrates our commitment to enabling precision health and providing innovations that support oncologists, nuclear medicine specialists and other physicians throughout a cancer patient's journey, from initial screening and diagnosis to informing therapy selection and monitoring the effectiveness of treatment."

Zionexa, a privately owned company, formed in 2018 and headquartered in Aubière, France, employs 24 people in France and the U.S., all of whom will transfer to GE Healthcare. Additionally, GE Healthcare will hire approximately 70 new dedicated employees within the company's U.S. Pharmaceutical Diagnostics team, headquartered in Marlborough, Massachusetts.

Olivier Carli, President of Denos, the majority owner of Zionexa, said: "We expect GE Healthcare Pharmaceutical Diagnostics' acquisition to allow Zionexa to accelerate the development of its promising R&D pipeline as well as its commercial footprint, while providing Zionexa's team with access to global and complementary expertise."

Currently, when treating metastatic breast cancer patients, oncologists base clinical decisions on biopsy results which only represent the sampled area of the tumor. However, estrogen receptor (ER) expression – one of the most common breast cancer biomarkers - can vary both within the primary tumor and across different lesions[3]. Cerianna, an adjunct to biopsy, widens the diagnostic lens for oncologists with a whole-body view of ER positive lesions, helping to provide the patient with a more informed diagnosis, potentially enabling more targeted and individualized treatment plans and avoiding the selection of inappropriate or less effective therapies.

Dr. Hannah M Linden, Breast Medical Oncologist, UW Medicine, University of Washington Fred Hutchison Cancer Research Center and Seattle Cancer Care Alliance in Seattle, who has conducted research and authored multiple papers on fluoroestradiol F-18, explained: "Making Cerianna more widely available is an important moment for cancer patients and a significant step forward for molecular imaging. We test ER expression in a metastatic biopsy once at the beginning of the patient's journey and we make decisions all along - when to give chemotherapy, when to use endocrine therapy, whether or not to use targeted agents - based on that one measurement. Since we know that ER expression can change with time and treatment, imaging with 18F-fluoroestradiol at critical decision points could help clinicians predict response to endocrine therapy and select optimal treatment timing and sequencing."

GE Healthcare Pharmaceutical Diagnostics imaging agents support three patient procedures every second worldwide across MRI, X-ray/CT, ultrasound and nuclear medicine imaging.

The financial terms of the acquisition are not being disclosed.

About GE Healthcare:

GE Healthcare is the $18 billion healthcare business of GE (NYSE: GE). As a leading global medical technology, pharmaceutical diagnostics and digital solutions innovator, GE Healthcare enables clinicians to make faster, more informed decisions through intelligent devices, data analytics, applications and services, supported by its Edison intelligence platform. With over 100 years of healthcare industry experience and around 47,000 employees globally, the company operates at the center of an ecosystem working toward precision health, digitizing healthcare, helping drive productivity and improve outcomes for patients, providers, health systems and researchers around the world. Follow us on Facebook, LinkedIn, Twitter, and Insights for the latest news, or visit our website www.gehealthcare.com for more information. For information about GE's forward-looking statements, see https://www.ge.com/investor-relations/important-forward-looking-statement-information

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) and find full Prescribing Information here.

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Important Safety Information for Cerianna™ (fluroestradiol F 18) Injection

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 at +1.844.946.6392 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

[1] Mariotto et al. Estimation of the Number of Women Living with Metastatic Breast Cancer in the United States. Cancer Epidemiology, Biomarkers & Prevention. 2017: 10.1158/1055-9965.EPI-16-0889.

[2] Survival Rates for Breast Cancer, Jan 27 2021. https://www.cancer.org/cancer/breast-cancer/understanding-a-breast-cancer-diagnosis/breast-cancer-survival-rates.html

[3] 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

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