GE Healthcare Advances Precision Health & Theranostics With New Products & Solutions at #SNMMI21

June 11, 2021

CHICAGO – June 11, 2021 – At the Society of Nuclear Medicine and Molecular Imaging's (SNMMI) 2021 summer conference, GE Healthcare is proud to showcase new molecular imaging products and solutions as well as new opportunities to expand access to radioactive tracers and other pharmaceutical imaging agents. This increase in access to the latest and most innovative precision diagnostics and radiopharmaceuticals – particularly with recent FDA clearances of critical new therapies – can provide clinicians unique opportunities to make personalized care decisions and treatment response assessments that may help improve patient outcomes.

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Theranostics With New Products &...
IMAGE/PNG · 2.12 MB

As an example, GE Healthcare is doubling its U.S. distribution footprint of Vizamyl (flutemetamol F18) following the FDA's recent approval of Aduhelm™ (aducanumab) the first approved treatment for the reduction of beta-amyloid plaques associated with Alzheimer's disease. This will significantly expand the availability of Vizamyl – a PET radiotracer used to diagnose the presence and density of beta-amyloid plaques in patients with suspected Alzheimer's disease or other causes of cognitive decline – to imaging centers and clinicians. GE Healthcare will also launch education and awareness initiatives for patients and their families, clinicians, payers, and policymakers about the role amyloid imaging has in the diagnosis and monitoring of Alzheimer's disease.

"For years we've been talking about precision health and theranostics as 'the future of healthcare.' Now, we are seeing it become a reality," says Jean Luc Procaccini, President & CEO, Molecular Imaging & Computed Tomography, GE Healthcare. "Fortunately, GE Healthcare is ready, already having spent years developing cutting-edge products with precision health and theranostics in mind. From cyclotrons and chemistry synthesis to imaging solutions to radioisotopes and pharmaceutical diagnostics, we are proud to offer the tools and information needed by clinicians to make more personalized care recommendations. Afterall, healthcare is personal – our treatments should be too."

Historically, medical treatments have been designed for the "average patient." As a result of this "one-size-fits-all" approach, treatments can be very successful for some, but not for others. Precision healthcare or personalized medicine, on the other hand, is an innovative approach that uses one's personal information and biomarkers — particularly genes, environments, and lifestyles — to help tailor treatment recommendations for individual patients[1]. This approach to healthcare has in turn given rise to theranostics, a new field of medicine that allows for targeted therapies because of clinically precise diagnostic tests.

To help clinicians more easily gather and interpret the vast amount of patient data needed to make more personalized care recommendations, GE Healthcare is proud to introduce a series of new products and AI-powered solutions to the market and help expand access to precision health resources.

Nuclear Medicine (SPECT/CT)

Recently cleared by the FDA, GE Healthcare's next-generation StarGuide[2] SPECT/CT system uses the latest digital technologies to help clinicians improve patient outcomes in bone procedures, cardiology, neurology, oncology, and other medical specialties. The system's cutting edge 12 CZT **Digital Focus Detectors** not only scan patients in 3D to provide more information to clinicians but they are also optimized for theranostic procedures.

The ability to generate high-quality SPECT/CT images starts with StarGuide's unique **Optical Scout** technology, which leverages the system's efficiency-focused Swift Plan workflow to determine the contour of the patient body and set the rest of the clinical scanning procedure into motion. After processing the Optical Scout data, StarGuide's detectors and table automatically position themselves for close proximity and contactless scanning of the patient. The slim Digital Focus Detectors then orbit the body as closely as possible, and from all necessary angles, to scan the target area — and not the air surrounding the patient. The result is high-resolution images for clinicians and the minimization of time on the table for patients[3].

The excellent energy resolution of the GE Healthcare-produced CZT crystals for StarGuide's Digital Focus Detectors offers clinicians the unique ability to simultaneously image multiple tracers in a single scan to help reduce the need for multiple patient visits and, in relevant cases, multiple patient sedations. Also, the combination of StarGuide's shape adaptive gantry and CZT detector technology supports the imaging of tracers used in theranostics with impressive quality. This includes Lutetium-177 (177Lu), a tracer used to diagnose and evaluate a patient's treatment response for neuroendocrine and prostate cancer[4].

GE Healthcare also recently announced **Xeleris V,** a new virtualized, flexible AI-powered solution that provides clinicians secure access to data from anywhere – helping them make personalized care decisions and treatment recommendations that are at the heart of precision health. This increase in access – paired with new AI-enabled applications and GE Healthcare's large install base of nuclear medicine cameras – can simplify and enhance workflows to help clinicians quickly discover, diagnose, and treat patients with accuracy.

Market research shows that 73 percent of radiologists expect operational efficiency to be the main challenge in the next 1-3 years[5], while 64 percent of surveyed clinicians note that physician burnout has intensified during the pandemic[6]. These statistics highlight a growing need for increased flexibility, access, and efficiency in healthcare today.

With these statistics in mind, Xeleris V's new AI-enabled clinical applications work to streamline workflows, provide accurate data, and help expedite

diagnoses across care areas: **Q.Volumetrix AI, Q.Lung AI, and EXINI Bone.**

PET/CT

GE Healthcare's **Discovery MI Gen 2** is the only PET/CT system that brings together the highest sensitivity[7] of digital detection with the company's industry-first CT image reconstruction technology: Deep Learning Image Reconstruction for **TrueFidelity CT Images.**

Generated using a dedicated deep neural network, TrueFidelity CT Images have the potential to improve reading confidence in a wide range of clinical applications such as head, whole body and cardiovascular, for patients of all ages. The system also offers Q.Clear for up to 2x improvement in image quality (SNR) as well as MotionFree for up to 67 percent improvement in lesion volume measurements[8].

Finally, Discovery MI Gen 2 is engineered for remote patient landmarking and positioning with **AutoIN,** which may aid in limiting contact with contagious diseases and unnecessary radiation exposure.

Radio Pharmacy

In December 2020, the FDA approved 68Gallium PSMA-11 (Ga 68 PSMA-11) – the first drug for PET imaging of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer, the third most common form of cancer in the United States[9], [10]. This approval is expected to increase demand for an already scarce PET imaging isotope: 68Gallium.

For many, a lack of access to radioisotopes can be a hinderance to practicing molecular imaging and precision health. Ongoing shortages of the generators that produce 68Gallium creates serious challenges for medical professionals treating a variety of patients.

GE Healthcare offers a solution with the expansion of its **PETtrace** cyclotron capabilities in combination with its FASTlab 2 Developer to now produce **68Gallium** and increase theranostics capabilities.

Cyclotron produced 68Gallium is cheaper than generator production and provides a greater return on investment over the course of one year[11]. This is largely due to a cyclotron's ability to produce two times the amount of gallium chloride compared to a generator [12]. In the last 15 years, 68Gallium publications increasing 100x and clinician interest and use of Gallium continues to grow[13].

Pharmaceutical Diagnostics & PET Tracers

In May 2021, GE Healthcare announced its acquisition of Zionexa, a leading innovator of in-vivo oncology and neurology biomarkers that help enable more personalized healthcare. With this acquisition, GE Healthcare 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 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. [14], with a five-year survival rate of 28 percent[15]. 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 aims to scale Cerianna to be accessible to a minimum of 75 percent of patients by 2023.

As the global leader in pharmaceutical imaging agents, GE Healthcare has a strong record of expanding clinical access to essential imaging agents, helping enable more personalized patient care. In 2021, the company shipped the 250,000th dose of DaTscan – which is an important neurology diagnostic used by clinicians to help inform treatment recommendations related to suspected Parkinsonian syndromes. Across all markets where it is available, DaTscan has been used to perform over one million scans[16] to date.

While there is still much work to be done in the field of theranostics and precision health, the full breadth of GE Healthcare's molecular imaging and pharmaceutical diagnostics portfolio offers clinicians unique opportunities to make personalized care decisions and treatment response assessments that are at the heart of personalized medicine and theranostics. GE Healthcare is the only partner with solutions spanning from pharmaceutical diagnostics, cyclotrons, chemistry synthesis, PET/CT, PET/MR, nuclear medicine, advanced digital solutions, and pharmaceutical partnerships to cover the breadth of steps from discovery to diagnosis to treatment.

For more information on GE Healthcare's molecular imaging and pharmaceutical diagnostics offerings, visit the company's virtual SNMMI booth or gehealthcare.com.

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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, Instagram and Insights for the latest news, or visit our website www.gehealthcare.com for more information.

About Vizamyl:

Vizamyl (flutemetamol F18) is a radioactive diagnostic agent indicated for Positron Emission Tomography (PET) imaging of the brain to estimate β-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD) or other causes of cognitive decline. A negative Vizamyl scan indicates sparse to no neuritic plaques, and is inconsistent with a neuropathological diagnosis of AD at the time of image acquisition; a negative scan result reduces the likelihood that a patient's cognitive impairment is due to AD. A positive Vizamyl scan indicates moderate to frequent amyloid neuritic plaques; neuropathological examination has shown this amount of neuritic plaque is present in patients with AD but may also be present in patients with other types of neurologic conditions, as well as older people with normal cognition. Vizamyl is an adjunct to other diagnostic evaluations

For more information about Vizamyl, please visit GE Healthcare.com and find full prescribing information here.

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.

Important Safety Information for Vizamyl ™ (flutemetamol F 18) Injection

CONTRAINDICATIONS

- Known hypersensitivity to Vizamyl or any excipient, including polysorbate 80

WARNINGS AND PRECAUTIONS

- **Hypersensitivity Reactions:** Reactions such as flushing and dyspnea have been observed within minutes following administration and may occur in patients with no history of exposure to Vizamyl. Before administering Vizamyl, ask patients about prior reactions to drugs, especially those containing polysorbate 80. Have resuscitation equipment and trained personnel available
- **Risk for Image Misinterpretation and Other Errors:** Errors may occur while interpreting Vizamyl positron-emission tomography (PET) images. Image interpretation is performed independently of the patient's clinical information. The use of clinical information in the interpretation of Vizamyl images has not been evaluated and may lead to errors. Extensive brain atrophy may limit the ability to distinguish grey and white matter on a Vizamyl scan. Motion artifacts may distort the image. Images should be interpreted only by readers who have completed a reader training program available from GE Healthcare
- **Radiation Risk:** Like all radiopharmaceuticals, Vizamyl contributes to a patient's long-term, cumulative radiation exposure and cancer risk. Ensure safe handling to protect patients and healthcare workers from unintentional radiation exposure

ADVERSE REACTIONS

- The most commonly reported adverse reactions in clinical trials were flushing (2%), increased blood pressure (2%), headache (1%), nausea and dizziness (1%)

DRUG INTERACTIONS

- Drug-drug interaction studies have not been performed in patients to establish the extent, if any, to which concomitant medications may alter Vizamyl image results

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** All radiopharmaceuticals, including Vizamyl, have potential to cause fetal harm. There are no available data on Vizamyl in pregnant woman to evaluate drug associated risk of major birth defects, miscarriage or adverse maternal or fetal outcome Advise women about the potential for adverse pregnancy outcomes based on the radiation dose and gestational timing of exposure
- **Lactation:** There are no data on presence of flutemetamol or its metabolites in human milk. The benefits of breastfeeding should be considered along with the mother's clinical need for Vizamyl and any potential adverse effects on the breastfed child. Because many drugs are excreted in human milk and there is a potential for radiation exposure to nursing infants, advise a lactating woman to interrupt breastfeeding and pump and discard breast milk for 24 hours after administration to minimize radiation exposure to a breastfeeding infant
- **Pediatric Use:** Vizamyl is not indicated for use in pediatric patients
- **Geriatric Use:** No overall differences in safety were observed between older and younger subjects

OVERDOSAGE

- The clinical consequence of overdosing with Vizamyl has not been reported. It is unknown whether or not flutemetamol is dialyzable. The major risks of overdosage relate to increased radiation exposure and long-term risk for neoplasia. In case of overdose of radioactivity, hydration and frequent urination should be encouraged

Prior to Vizamyl administration, please read the full Prescribing Information for additional Important Safety Information.

To report SUSPECTED ADVERSE REACTIONS, contact GE Healthcare at 800-654-0118 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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.

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[1] Phillips, C. “Precision Medicine and its Imprecise History.” HDSR. 31 Jan 2020. https://hdsr.mitpress.mit.edu/pub/y7r65r4k/release/3

[2] StarGuide is FDA cleared and CE marked. Available for sale in the United States and EU countries. Not for sale in other non-EU countries.

[3] StarGuide improves SPECT resolution with scatter, planar sensitivity, and SPECT sensitivity compared to NM/CT 870 DR using LEHR/LEHRS collimators and NM/CT 870 CZT using WEHR collimator. StarGuide SPECT reconstruction with scatter used the system’s factory NEMA NU 1-2018 resolution protocol which uses the same method (BSREM with Clarity 3D) as its clinical bone protocol. NM/CT 870 DR and NM/CT 870 CZT SPECT reconstruction used Evolution for Bone (OSEM). StarGuide’s planar sensitivity was measured for each of its 12 detectors and adapted from NEMA NU 1-2018.

[4] Radiopharmaceuticals may not be approved by ministers of health in all regions. 177Lu-PSMA is currently not an FDA approved tracer.

[5] GE Healthcare data on file.

[6] Physician Income Drops, Burnout Spikes Globally in Pandemic, Medscape Medical News, Marcia Frellick, September 11, 2020.

[7] Discovery MI Gen 2 has the highest NEMA sensitivity in its class in the market, comparing with common PET/CT systems with same or similar AFOV (based on IMV’s Medical Information Division’s 2019 report as the manufacturers representing more than 90% of the US Installed Base).

[8] As demonstrated in phantom testing using a typical and fast respiratory model and OSEM reconstruction. Quantitative accuracy improvements are based on SUV mean.

[9] “FDA Approves First PSMA-Targeted PET Imaging Drug for Men with Prostate Cancer.” U.S. Food & Drug Administration. Dec 01, 2020. https://www.fda.gov/news-events/press-announcements/fda-approves-first-psma-targeted-pet-imaging-drug-men-prostate-cancer?utm_medium=email&utm_source=govdelivery

[10] Cancer Stat Facts: Prostate Cancer. National Cancer Institute. Accessed Jun 11, 2021. https://seer.cancer.gov/statfacts/html/prost.html#content

[11] Based this on calculations of the cost of running generators that produce 68Gallium compared to those of cyclotrons.

[12] Based on a PETtrace cyclotron liquid target versus a new 50 mCi generator

[13] clinicaltrials.gov (October 27, 2020) – search terms: 68Ga/Ga68/68Gallium/Gallium68

[14] 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.

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

[16] GE Healthcare on file

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