From General to Personalized Care: GE HealthCare is Focused on Disease Detection and More Holistic and Effective Treatment Options

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The company will showcase its latest innovative solutions to enable rapid diagnosis, Theranostics, and precision care at #SNMMI23

- Clinicians and patients are aligned in what they want: A healthcare experience that is more human and flexible, focusing on the needs of both clinicians and patients[i]
- Precision medicine is a growing field that aims to improve health outcomes by precisely diagnosing and treating medical conditions, tailored to the individual patient
- A leading medical technology, pharmaceutical diagnostics, and digital solutions innovator, GE HealthCare is strategically positioned to help provide clinicians the images, information, and pharmaceutical diagnostic agents necessary for the practice and advancement of precision care

CHICAGO--(BUSINESS WIRE)--Jun. 24, 2023-- At the Society of Nuclear Medicine and Molecular Imaging (SNMMI) 2023 annual meeting, GE HealthCare (Nasdaq: GEHC) is proud to showcase new, innovative technologies and diagnostics that enable personalized medicine and precision care to help clinicians improve patient outcomes around the world. This includes the introduction of new artificial intelligence (AI) solutions for enhanced image quality; the advancement of Theranostics; and achievement of new milestones in the accessibility and development of pharmaceutical diagnostics for precision care.

Sixty percent of clinicians say healthcare that is personalized for each patient is very important for the future.[i] However, achieving a more personalized and flexible healthcare experience requires fundamental changes in the way healthcare operates. The system must evolve to be smarter, easier and more collaborative. Fortunately, this evolution is already underway, and both clinicians and patients agree with the direction.

"The future of medicine consists of a powerful blend of precision diagnostic imaging and targeted therapy for the more personalized treatment of cancer and other diseases – and at the heart of this rapidly emerging field is molecular imaging and Theranostics," shares Dr. Narinder Paul, Lawson Scientist; Chief, Medical Imaging at St. Joseph's; Physician Executive, Medical Imaging at London Health Sciences Centre; and Chair, Department of Medical Imaging at Western University.[ii] "Together, this two-pronged approach to diagnosing and treating patients – along with the use of pharmaceutical diagnostics and radiotracers – can not only identify the location and extent of diseased tissues but also selectively destroy the abnormal cells while helping reduce the damage to surrounding healthy cells. It truly is cutting-edge medicine that has the potential to revolutionize patient care."

Enabling personalized medicine

Whether researching new tracers and diagnostic techniques or helping a patient plan their treatment path, GE HealthCare understands the importance of providing innovative technologies and solutions to enable the best possible patient care.

With this in mind, GE HealthCare is proud to unveil SIGNA PET/MR AIR, expanding access to its popular magnetic resonance (MR) imaging technologies – including AIR Recon DL and AIR Coils – to the practice of molecular imaging and across more care areas. Pairing the industry's most sensitive Time-of-Flight (ToF) PET detector and the company's most capable MR technology with AIR, the SIGNA PET/MR AIR leverages the latest advancements in GE HealthCare's medical technology and digital solutions to help clinicians see some of the smallest lesions, research new tracers, and more accurately plan treatment paths for every patient. Unlike conventional inflexible coils, AIR Coils are pliable and adapt to the shape of the human body, resembling a gentle blanket. For instance, they can envelop a knee to capture a comprehensive image or drape over the patient's body. By utilizing radio frequency (RF) technology, these coils significantly enhance both image quality and patient comfort.

Image clarity is then further enhanced with the use of deep learning and AI, including the company's AIR Recon DL for pin-sharp, accurate images and up to 50 percent faster scan times, a smoother workflow, and an enhanced patient experience; and MotionFree Brain[iii] for motion management without the need for any external devices or additional scan time, allowing clinicians to see clear and still brain images.

Collectively, the availability of these features on GE HealthCare's SIGNA PET/MR helps enable more confident diagnoses and personalized treatment recommendations across oncology and neurology care areas, including prostate cancer and Alzheimer's disease.

"Our precision care strategy will provide clinicians with key insights to help diagnose disease and determine the most appropriate treatment – all with the goal of delivering the best possible outcome for the patient," explains Jan Makela, president and CEO, Imaging, GE HealthCare. "AI and deep learning for image acquisition and reconstruction are vital capabilities for GE HealthCare and are proven to give clinicians a noninvasive and clear view inside the human body. In turn, this helps with more rapid diagnoses and more holistic, effective treatment planning and monitoring."

The availability of AIR Recon DL for PET/MR marks the latest expansion of GE HealthCare's Effortless Recon DL portfolio of deep learning-based solutions – which also includes AIR Recon DL and Sonic DL for MR, TrueFidelity for CT, Precision DL for PET/CT, and Helix for X-ray – to significantly improve image quality and help better inform clinical decision-making for improved patient outcomes.

Recently cleared by the U.S. FDA, Precision DL is available on Omni Legend, which already boasts more than two times the sensitivity of prior digital scanners[iv], enabling faster scan times[v] and impressive small lesion detectability.[vi] A new, revolutionary deep learning-based image processing software, Precision DL provides the image quality performance benefits typically associated with hardware-based ToF reconstruction, including

improved contrast-to-noise ratio, contrast recovery, [vii] and quantitative accuracy.[viii]

Together, Precision DL with Omni Legend's ultra-high sensitivity, third generation digital detector technology marks a new era for PET/CT performance and outcomes, transitioning from ToF technology to the next generation of PET/CT performance and enabling clinicians to decode coincidence events at exceptionally fine resolutions for informed diagnoses and treatment planning across care areas.

Omni Legend represents the company's fastest-ever-selling PET/CT [ix] with more than 200 customer commitments to purchase the system in only nine months.

Meanwhile, GE HealthCare's cutting-edge StarGuide SPECT/CT can help clinicians evaluate the success of therapies. The system's 12 CZT detector design not only scans patients in 3D to provide more information to clinicians but is also optimized for certain Theranostics procedures – a form of precision medicine – which in turn helps clinicians pinpoint the size, shape, and position of lesions with exceptional accuracy. Paired with GE HealthCare's innovative Q.Thera AI for accurate dosimetry, they help evaluate and monitor the dose absorbed by sensitive organs as well as lesions. Designed for efficient dosimetry and quantitation, Q.Thera AI is GE HealthCare's solution for Theranostics treatment dose monitoring, empowered by AI.

Collectively, these technologies and solutions are key for the adoption and advancement of Theranostics, a rapidly growing practice that enables more personalized cancer and disease care.

Advancing Theranostics

Where most medical therapies are designed with the 'average' patient in mind, Theranostics brings together diag **nostics** and highly targeted **thera**pies in one care pathway to help optimize disease diagnosis and treatment monitoring with molecular imaging technologies and advanced digital solutions. This practice helps provide a more personalized therapy to address the needs of individual patients.

Clinicians and patients are especially seeing success with Theranostics in prostate cancer, hyperthyroidism, and thyroid cancer.[x] Additionally, the practice is rapidly growing with its approval for other clinical indications, including bone metastases from prostate cancer, neuroendocrine tumors, non-Hodgkin's lymphoma, and adrenergic tumors. [xi]

Now – as demand for Theranostics infrastructure and best practices surges – GE HealthCare is excited to collaborate with Canada's St. Joseph's Health Care London and the Lawson Health Research Institute to assist with the development of a new Theranostics Center of Excellence. This center will support research activities, clinical collaboration, educational and training programs for the evolving clinical practice of Theranostics to help increase healthcare system adoption and improve patient care and awareness.

Providing molecular information for precision care

Today's healthcare system is frequently driven by a one-size fits-all approach to care. [i] Looking ahead, medicine must be more customized to the individual to focus on disease prevention, detection and effective treatment.

For certain care pathways – including oncology, cardiology, and neurology – this process begins with the production of radioisotopes for use in pharmaceutical diagnostic tracers, which are administered to the patient, attach to specific cancer cells, and release radioactive emissions to provide clinicians detailed molecular information unique to each patient.

To enable and encourage the adoption and practice of precision care – including Theranostics – GE HealthCare is making significant effort to help increase access to these key enablers for better-informed diagnoses and monitoring as well as improved therapy decision-making and clinical outcomes:

- **Increasing radioisotope production for use in diagnostic tracers**: Growing demand for Gallium-68 – a key radioisotope used in the production diagnostic tracers for prostate cancer – and the limitations of generators historically have created serious challenges for clinicians and limited patient access. In response, GE HealthCare is proud to introduce a new Solid Target Platform for its PETtrace cyclotron which – in combination with its FASTlab 2 New Edition platform – can produce 100x the amount of Gallium compared to a generator for increased Theranostics capabilities and access in prostate cancer patient care.[xii]

- **Aiming to predict and monitor early response to cancer immunotherapies**: With immunotherapy emerging as one of the most important treatment options in oncology, GE HealthCare is conducting a Phase I clinical trial[xiii] of a first-of-its kind fluorine-18 PET radiopharmaceutical ([18F]GEH200521) specific for CD8, which is expressed on CD8+ T cells - a subpopulation of white blood cells which fight cancer.

  There are around 5,000 immunotherapies in development today, [xiv] almost all of which work by activating CD8+ T cells both within and outside a tumor. The clinical trial will use this investigational radiopharmaceutical to help understand if patients have CD8+ T cells in their tumors and will, therefore, be more likely to respond to immune checkpoint inhibitors, the main class of immunotherapies currently approved for use. The study will also then help identify early response to immunotherapies, using sequential whole-body imaging to monitor CD8 changes over time, enabling physicians to switch patients who are not responding to alternative treatment options sooner.

- **Delivering a comprehensive assessment for ER+ positive recurrent or metastatic breast cancer diagnoses and treatment planning**: After the SNMMI itself published Appropriate Use Criteria to guide referring and imaging physicians in appropriate use of estrogen receptor (ER)-targeted PET imaging with 16α-18F-fluoro-17ß Fluoroestradiol, GE HealthCare

announced that NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)[xv] for clinicians and patients now recommend the use of FES PET for ER+ positive disease in certain circumstances for the systemic staging workup of patients with recurrent or metastatic breast cancer. GE HealthCare's Cerianna™ (fluoroestradiol F 18) injection, available in the U.S., is the only FDA approved FES PET imaging agent.

Cerianna is indicated for use with PET imaging for the detection of ER+ lesions as an adjunct to biopsy in patients with recurrent or metastatic breast cancer. Providing a whole-body view of ER+ lesions, Cerianna may deliver a comprehensive assessment to assist in making an informed diagnosis and treatment plan for the patient, potentially enabling a more targeted and individualized treatment strategy thus avoiding the selection of inappropriate or less effective therapies.

As the only healthcare industry partner with solutions spanning from cyclotrons, chemistry synthesis, pharmaceutical diagnostics, PET/CT, PET/MR, SPECT/CT, and advanced oncology and digital solutions, GE HealthCare is uniquely positioned to cover the full breadth of the patient care journey.

To learn more about GE HealthCare's precision care strategy and solutions, visit gehealthcare.com or explore the company's booth at #SNMMI23.

[i] *Reimagining Better Health 2023*. GE HealthCare. Published June 6, 2023. Accessed June 8, 2023. https://www.gehealthcare.com/insights/reimagining-better-health

[ii] Not a consultant for GEHC: The statements by GE's customers described here are based on their own opinions and on results that were achieved in the customer's unique setting. Since there is no "typical" hospital and many variables exist, i.e. hospital size, case mix, etc. there can be no guarantee that other customers will achieve the same results.

[iii] MotionFree Brain is not yet CE marked. Not available for sale in all regions.

[iv] Omni Legend 32 cm has up to 2.2 increase in system sensitivity as compared to Discovery MI 25 cm. Measurement follows NEMA NU 2-2018.

[v] Up to 53% reduction of PET scan time on Omni Legend 32 cm compared to Discovery MI 25 cm, as demonstrated in phantom testing.

[vi] Omni Legend 32 cm increases small lesion detectability 16% on average and up to 20%, as compared to Discovery MI 25 cm with matched scan time/injected dose, as demonstrated in phantom testing using a model observer with 4 mm lesions; average of different reconstruction methods.

[vii] Precision DL with Omni Legend 32cm data improves Contrast Recovery (CR) by 11% on average and Contrast-to-Noise Ratio (CNR) by average of 23% as compared to non-ToF reconstruction. CR and CNR demonstrated using clinical data with inserted lesions of known size, location, and contrast. Using data from Omni Legend 32 cm, CR and CNR were measured using High Precision DL and QCHD.

[viii] Precision DL with Omni Legend 32cm improves feature quantitation accuracy by 14% as compared to Discovery MI with ToF reconstruction, at comparable noise level. Quantitation accuracy demonstrated using clinical data with inserted lesions of known size, location, and contrast (ground truth). Feature SUVmean from Omni Legend 32 cm with High Precision DL compared to SUVmean from Discovery MI 25 cm with QCFX.

[ix] Based on orders data of GE HealthCare PET/CT systems since 2010.

[x] Flávio, J et al. "Theranostics in Nuclear Medicine: Emerging and Re-emerging Integrated Imaging and Therapies in the Era of Precision Oncology." RadioGraphics 2020 40:6, 1715-1740. https://pubs.rsna.org/doi/full/10.1148/rg.2020200021

[xi] Ballinger, JR. "Theranostic radiopharmaceuticals: established agents in current use." Br J Radiol. 2018 Nov;91(1091):20170969. doi: 10.1259/bjr.20170969. Epub 2018 Mar 12. PMID: 29474096; PMCID: PMC6475961. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6475961/

[xii] Svedjehed et al. "Demystifying solid targets: Simple and rapid distribution-scale production of [68Ga]GaCl3 and [68Ga]Ga-PSMA-11." *Nuclear Medicine and Biology*. Volumes 104–105, January–February 2022, Pages 1-10. https://doi.org/10.1016/j.nucmedbio.2021.10.002

[xiii] Further information available at clinicaltrials.gov - ClinicalTrials.gov Identifier: NCT05629689 - A Study to Evaluate GEH200520/GEH200521 (18F) Safety and Tolerability When Used for PET Scans in Patients With Solid Tumour Malignancies

[xiv] Shankar L. et al. Harnessing imaging tools to guide immunotherapy trials: summary from the National Cancer Institute Cancer Imaging Steering Committee workshop. Lancet Oncology 2023; 24(3): e133-e143. doi: 10.1016/S1470-2045(22)00742-2

[xv] NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

Important Safety Information

CERIANNA™ (fluoroestradiol F18) injection is a diagnostic imaging agent (sometimes called a radiopharmaceutical or tracer). CERIANNA is used as part of a positron emission tomography (PET) scan for women to detect a specific protein called the estrogen receptor on breast cancer tumors that have recurred or spread from their original site (metastasized). CERIANNA is used in addition to biopsy.

Adverse reactions: The most common side effects seen with CERIANNA were pain at the site of injection and temporary altered taste sensation.

Radiation risks: CERIANNA is radioactive, and exposure to radiation has a dose-dependent increased risk of cancer. Please discuss with your doctor about ways to help minimize this risk.

Risk of misdiagnosis: CERIANNA imaging results can have false negatives and false positives. Please discuss any concerns with your doctor.

Use in specific populations: Tell your doctor if you are or may be pregnant; if you plan on becoming pregnant; or you are currently breastfeeding.

Additionally, CERIANNA has not been studied in patients under the age of 18.

CERIANNA is expected to behave similarly in adult patients, regardless of age.

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

Find full Prescribing Information here.

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