NEWS BRIEF

GE Healthcare Offers 'Total MI for Theranostics,' A Comprehensive Portfolio of Molecular Imaging Solutions to Help Advance the Adoption & Practice of Precision Medicine

GE Healthcare is proud to provide cutting-edge molecular imaging solutions that enable and increase precision medicine and theranostics access to help improve patient outcomes – namely in prostate cancer – the most prevalent cancer in men and the third most prevalent cancer overallⁱ. The company refers to it as '**Total MI for Theranostics**.'

Where most medical therapies are designed with the 'average' patient in mind, theranostics brings together diagnosis and treatment, providing a more targeted and personalized treatment than ever beforeⁱⁱ. Clinicians and patients are especially seeing success with theranostics in prostate cancerⁱⁱⁱ – a highly manageable disease, but one that is difficult to treat when diagnosed at a late stage – claiming more than 1.4 million lives annually^{iv}.

During the COVID-19 pandemic, clinical adoption of theranostics slowed due to a delay in elective procedures and the increased risk posed to its often-immunocompromised patients. However, a surge in demand for theranostics infrastructure^v is now anticipated following the U.S. Federal Drug Administration's (FDA) approval of several new drugs and therapies. This includes the diagnostic tracer Gallium-68 PSMA-11 and therapy drug Lutetium-177 PSMA-617, which are key to applying theranostics in prostate cancer.

As the industry prepares to usher in this new era of precision health and personalized medicine, GE Healthcare is proud to offer innovative molecular imaging solutions to healthcare systems around the world.

Discovery with the Molecule Journey: Enabling Precision Health

The enablement of theranostics in prostate cancer care begins with the production of radioisotopes for use in diagnostic tracers – namely Gallium-68 PSMA-11 – which is administered to the patient, attaches to specific cancer cells, and releases radioactive emissions to provide detailed molecular information unique to each patient.

However, growing demand for Gallium-68 and the limitations of generators have created serious challenges for clinicians and limited patient access. In response, GE Healthcare is proud to offer 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^{vi}.

While solid targets have been around for some time, they have traditionally been viewed as research tools and required complicated infrastructure and highly trained operators. Now, with GE Healthcare's **TRACERcenter Solutions** and new PETtrace Solid Target Platform, healthcare systems can more easily access the equipment, tracers and staff training necessary to deliver a more cost-effective, personalized solution.

Diagnosis: Accurately Staging & Quantifying Disease

To read the emissions released by the Gallium-68 PSMA-11 tracer, the patient must be imaged using a highly sensitive PET/CT scanner. This technology provides the clinician detailed information that is

used to better understand the structure and function of each patient's tissue and disease state to help form personalized therapy recommendations. The more sensitive the PET/CT, the more accurate the images and quantification.

To this end, GE Healthcare recently introduced <u>Omni Legend</u>^{vii}, the first system on its all-new, all-digital PET/CT platform. This cutting-edge system features a brand-new category of digital detector technology capable of producing high resolution images and more than two times the sensitivity of prior digital scanners^{viii}, enabling faster total scan times^{ix} and exceptional image quality for small lesion detectability^x. It is designed to improve operational efficiency, enhance the patient experience, and increase diagnostic power, ideally helping to enable fast scans and improved patient outcomes.

Omni Legend encourages the adoption of theranostics, enabling clinicians to image short life tracers and reach new levels of sensitivity and detectability for incredibly clear images and greater clinical information across more oncology, cardiology, and neurology procedure types than ever before. Already, the system boasts the highest sensitivity per cm in the market^{xi} and images Gallium 68 with excellent image quality for diagnosis, staging, or restaging.

Additionally, Omni Legend offers a collection of intuitive workflow solutions enhanced by artificial intelligence (AI), including its new Precision DL^{vii} solution for deep learning image processing in PET/CT as well as its AI-based Auto Positioning Camera, which automatically centers the patient for a completely hands-free positioning experience.

More than a new processing technique, Precision DL^{vii} is engineered using Deep Learning with a sophisticated deep neural network trained on thousands of images created with different reconstruction methods. It was designed to provide the image quality performance benefits most associated with hardware-based Time-of-Flight, such as better contrast-to-noise ratio, contrast recovery, and quantitative accuracy.

The capabilities of Omni Legend are further elevated by the inclusion of Q.Clear (BSREM) and MotionFree for up to 67 percent improvement in lesion volume measurements, helping inform clinicians' prostate cancer therapy recommendations^{xii}.

Treatment: Delivering & Monitoring Targeted Therapy

With regard to therapy, the FDA recently approved Lutetium-177 PSMA-617 – an exceptional therapy for advanced prostate cancer – in March 2022. It works by binding to and delivering a small amount of radiation to prostate cancer cells anywhere in the body to help patients with advanced prostate cancer live longer and maintain quality of life^{xiii}.

To help clinicians evaluate the success of these therapies, GE Healthcare developed its breakthrough <u>StarGuide</u> SPECT/CT system with 12 cutting-edge CZT detectors that not only scan patients in 3D to provide more information to clinicians but are also optimized for Theranostics procedures– including imaging this latest Lutetium-177-based prostate cancer therapy with quantitative total body coverage and fast scan times similar to the Gallium-68 PET/CT scans of the same patient.

Compared to conventional technologies, StarGuide's Digital Focus CZT detectors offer improved volume sensitivity and SPECT resolution^{xiv}, which is especially valuable for imaging <u>both</u> peaks of Lutetium-177 emissions, which in turn helps clinicians pinpoint the size, shape, and position of lesions with exceptional accuracy. Paired with GE Healthcare's innovative Q.Clear solution for SPECT

reconstruction, the resulting images provide outstanding quantification for the diagnosis and staging of disease and monitoring of treatment.

Increasing Accuracy & Efficiency

Artificial intelligence (AI) also offers new opportunities to streamline workflows, provide accurate data, and help expedite diagnoses across care areas – all valuable offerings in today's resource constrained healthcare environment.

For this reason, GE Healthcare offers its <u>Xeleris V</u> Theranostics package, a virtual processing and review solution featuring cutting-edge AI applications that can be used in healthcare system Theranostics pathways to streamline workflows, provide accurate data, and help expedite diagnoses across care areas:

- **Q.Thera AI**^{xv}: The industry-wide trend toward precision care has increased the complexity of manual workflows like organ segmentation and dose calculations. Q.Thera AI is designed to help clinicians automatically and accurately segment organs for quantitation and dosimetry calculations, all with the goal to help reduce the time required for the user to process and calculate dose enabling them to simplify processes and provide personalized monitoring of treatment to patients.
- **Q.Volumetrix AI**: Already, 90 percent of healthcare professionals with AI deployments confirm automating and prioritizing workflows is the technology's key benefit^{xvi}. Q.Volumetrix AI builds on this success, expediting processes and enhancing workflow by enabling advanced segmentation and quantitation capabilities for SPECT/CT and PET/CT data without impeding workflow for both baseline and longitudinal studies.

The advancement of imaging technologies and continuous evolution and discovery of new tracers and targeted therapies is ushering in a new era in healthcare – one in which precision health and theranostics exist at its core. Prostate cancer is only the beginning, with many more applications under development for the future.

GE Healthcare is proud to offer clinicians unique opportunities to make personalized care decisions and treatment response assessments for the benefit of patients around the world. The company is uniquely positioned to advance these efforts as the only partner with solutions spanning from molecular imaging diagnostics, cyclotrons, chemistry synthesis, PET/CT, PET/MR, nuclear medicine, advanced digital solutions, and pharma partnerships to cover the breadth of steps from discovery to diagnosis to treatment.

For more information on GE Healthcare's Molecular Imaging portfolio, visit <u>gehealthcare.com</u>.

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ⁱ International Agency for Research on Cancer. Accessed Jun 3, 2022. https://gco.iarc.fr/today/online-analysis-multi-bars?v=2020&mode=cancer&mode_population=countries&population=900&populations=900&key=total&sex=0&cancer=39&type=0&stati

ⁱⁱ Pharmacy Management System Market - Growth, Trends, Covid-19 Impact, And Forecasts (2022 - 2027). Mordor Intelligence. Accessed November 17, 2022. https://www.mordorintelligence.com/industry-reports/pharmacy-management-system-

market#:~:text=Where%20most%20medical%20therapies%20are,personalized%20therapy%20than%20ever%20before. ^{III} O'Dwyer et al. "The Role of Theranostics in Prostate Cancer." Semin Radiat Oncol. 2021 Jan; 31(1): 71–82.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8391014/

^{iv} "Cancer." World Health Organization. Feb 3, 2022. Accessed Jun 1, 2022. https://www.who.int/news-room/fact-sheets/detail/cancer ^v "JNM Publishes Joint Guide for the Establishment of Theranostics Centers." Society of Nuclear Medicine. Apr 29, 2022. https://www.snmmi.org/NewsPublications/NewsDetail.aspx?ItemNumber=40416

 ^{vi} 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
^{vii} Omni Legend and Precision DL are CE marked. Omni Legend is 510(k)-cleared by the U.S. FDA. Precision DL is 510(k)-pending with the U.S. FDA. Not available for sale in the United States.

viii 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.

^{ix} Up to 53% reduction of PET scan time on Omni Legend 32 cm compared to Discovery MI 25 cm, as demonstrated in phantom testing. ^x 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.

^{xi} Data on file. Highest sensitivity per cm, as compared to non-Total body PET-CT systems.

xⁱⁱ Compared to non-processed (STATIC, no motion correction) data. As demonstrated in phantom testing using a typical and fast respiratory model, 18 mm Ge-68 spheres, and OSEM reconstruction.

xiii "Breaking News: First-in-Class Radioligand Therapy Approved for Advanced Prostate Cancer," Prostate Cancer Foundation. March 23, 2022. https://www.pcf.org/c/breaking-news-first-in-class-radioligand-therapy-approved-for-advanced-prostate-

cancer/#:~:text=Lutetium%2DPSMA%2D617%20(Lu%2DPSMA)%20is%20now.and%20taxane%2Dbased%20chemotherapy ** 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). NM/CT 870 DR used LEHR/LEHRS collimators and NM/CT 870 CZT used the WEHR collimator. ** CE marked. Not for sale in the U.S. Not cleared or approved by the U.S. FDA.

xi MIT Technology Review in partnership with GE Healthcare, "The AI Effect: How Artificial Intelligence is Making Health Care More Human"

stic=5&prevalence=0&population_group=0&ages_group%5B%5D=0&ages_group%5B%5D=17&nb_items=10&group_cancer=0&include_nm sc=0&include_nmsc_other=1&type_multiple=%257B%2522inc%2522%253Afalse%252C%2522mort%2522%253Afalse%252C%2522bottom%2 2522%253Atrue%257D&orientation=horizontal&type_sort=0&type_nb_items=%257B%2522top%2522%253Atrue%252C%2522bottom%2 522%253Afalse%257D