NEWS BRIEF

GE Healthcare's comprehensive approach to breast cancer care addresses key challenges and helps advance a "brighter" future for patients and providers

#RSNA22 to be debut of GE Healthcare's One-Stop Clinic™ Experience for Breast– an immersive experience for healthcare providers that presents our value-based breast care offering featuring a portfolio of solutions to advance women's health and breast cancer care

*New Pristina Bright** offering provides a comprehensive solution to help healthcare providers start a new contrast program*

One in eight women develop breast cancer in their lifetime.[1] Regular screening mammograms can help save lives[2] as well as help women determine if they have dense breasts - an independent risk factor that is not as well-known but can double one's risk for breast cancer.[3]

40% of women have dense breast tissue[4] - which means they have a higher proportion of fibro glandular tissue than fatty tissue. While mammography is considered the most reliable imaging technique for breasts, limitations can exist due to breast density.[5] This is especially the case in dense breasts where tissues may overlap - hiding signs of breast cancer and making diagnosis more difficult or even missed.[6]

To provide a personalized breast screening approach for a diverse population, including those with dense breasts, GE Healthcare offers a comprehensive portfolio of breast imaging technologies, including the **Senographe Pristina™**, a mammography system designed to provide a better patient experience,[8] and **Invenia™ ABUS**, the first FDA-approved ultrasound supplemental screening specifically designed for detecting cancer in dense breast.

When a result remains inconclusive after screening, GE Healthcare's **SenoBright™ HD Contrast Enhanced Mammography (CEM)** can provide immediate follow-up when in search for a definitive answer. CEM combines mammography and vascular-based screening methods to highlight areas of unusual blood-flow patterns that may indicate malignancy - helping reduce the masking effect of fibro glandular breast tissue so lesions can be more clearly identifiable.[7] [8] [9] A SenoBright exam can be performed in the same room as a mammogram, with the same equipment, and can even be performed the same day in about seven minutes[10] as part of GE Healthcare's aim to provide precision, comfort and efficiency across the entire clinical breast health continuum. If medical indications

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**Pristina Bright is a commercial offering including SenoBright HD, Pristina Serena and Serena Bright

[1] https://www.breastcancer.org/facts-statistics

[2] Løberg M, Lousdal ML, Bretthauer M, Kalager M. Benefits and harms of mammography screening. Breast Cancer Res. 2015 May 1;17(1):63. doi: 10.1186/s13058-015-0525-z. PMID: 25928287; PMCID: PMC4415291.

[3] Nelson HD, Zakher B, Cantor A, et al. Risk factors for breast cancer for women aged 40 to 49 years: a systematic review and meta-analysis. Ann Intern Med. 2012;156(9):635-648.

[4] Pisano et al. NEJM 2005; 353: 1773.

[5] Buchberger W, Geiger-Gritsch S, Knapp R, Gautsch K, Oberaigner W. Combined screening with mammography and ultrasound in a population-based screening program. Eur J Radiol. 2018 Apr;101:24-29

[6] Up to 50% of breast cancers may be missed in extremely dense breasts. Kolb et al, Radiology, Oct 2002;225(1):165-75.

[7] Compared to without contrast

[8] J. Sung et al., Radiology 2019; 00:1–8

[9] V. Sorin et al. American Journal of Roentgenology: W267-W274. 10.2214/AJR.17.19355

[10] Data on file, GE Healthcare 2017

recommend pathology, biopsy under contrast with **Serena Bright™** can also be performed from first image to last image within fifteen minutes.[11]

In an effort to help further advance breast cancer and support healthcare providers in a starting a new contrast program, GE Healthcare's new Pristina Bright** offering provides a comprehensive solution. Pristina Bright combines SenoBright™ HD, Pristina Serena™, and Serena Bright™ with an education program that includes dedicated on-site support, CME accredited self-assessment, as well as access to the users' club where providers will be able to share with experts around the globe and leverage resources needed to market their facility among referring doctors and patients.

In addition to this offering and in continued pursuit to improve breast cancer outcomes, GE Healthcare has joined the **Contrast-Enhanced Mammography Imaging Screening Trial (CMIST)**[12] in collaboration with the American College of Radiology (ACR) and the Breast Cancer Research Foundation (BCRF)to gain an increased understanding of the effectiveness of CEM in the detection of breast cancer in dense breasts. Early studies of CEM for women with dense breasts have shown the potential benefit of CEM in the detection of breast cancer. The CMIST study seeks to determine if contrast-enhanced mammography provides more accurate cancer detection compared to digital breast tomosynthesis (DBT), including whether it reduces false-positive exams, in women with dense breasts.

The clinical power of contrast-enhanced mammography as well as our full suite of breast cancer care technologies will be featured in the debut of the One-Stop Clinic™ Experience for Breast at #RSNA22 (North Hall Room 8349). From days to hours, GE Healthcare's One-Stop Clinic Experience will enable practitioners and healthcare providers to step into the shoes of patients for a truly immersive breast care experience that puts the spotlight on value-based care, rapid diagnosis to treatment planning, personalized and precise care, all while improving workflow, operational, financial outcomes.

As part of the One-Stop Clinic Experience for Breast, GE Healthcare will be showcasing its full suite of technologies across the patient care continuum, including:

Senographe Pristina™: Regular screening increases the chances of detecting breast cancer early, when treatment is likely to work best.[13] The Senographe Pristina mammography system was designed to ease anxiety the moment the patient enters the exam room. It features an inviting gantry with elegant lighting and rounded shapes, as well as a soft-curved surface that welcomes patients into a space of comfort and support. 83% of patients rated their experience with Senographe Pristina better and more comfortable than previous exams.[14] Today, Pristina continues to evolve and expand along the breast care pathway - including the option to use **Pristina Dueta™**, an industry-first, patient- assisted compression remote control device that

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[11] Data on file. GE Healthcare 2020

[12] https://www.prnewswire.com/news-releases/american-college-of-radiology-acr-launches-contrast-enhanced-mammography-imaging-screening-trial-cmist-in-collaboration-with-ge-healthcare-and-the-breast-cancer-research-foundation-301653764.html

[13] https://www.cdc.gov/cancer/dcpc/prevention/screening.htm

[14] Data on file, GE Healthcare. 83% of patient assessed the exam as more comfortable than previous. IPSOS Patient Satisfaction Study sponsored by GE Healthcare, conducted with 315 patients across 2 sites in Europe

gives patients a sense of control around their breast compression during a mammogram while under the supervision of a technologist to minimize their discomfort.[15]

Invenia™ ABUS: Invenia™ ABUS 2.0 is a non-invasive and patient-friendly technology and helps to move Breast Care from reactive to proactive. When used as supplement to mammography, Invenia ABUS increases cancer detection in dense breasts by 35.7% and the additional mammography occult cancers found with ABUS were predominantly invasive and node negative[16]. Detecting cancer at this early stage has important prognostic implications and can reduce the total cost of care[17]. When breast cancers are found at Stage 1 and 2, 70% of patients may avoid chemotherapy[18]. The new and powerful **AI Assistant on Invenia ABUS 2.0** seamlessly integrates intelligent algorithms powered by FDA-approved third-party AI tools **QVCAD™** and **KOIOS DS™ Breast** to assist in detecting and characterizing breast lesions, helping radiologists increase their reading speed and streamline their workflow with a great degree of confidence. The implementation of QVCAD experience up to 93% sensitivity for lesion detection[19] and is leading into reducing reading time by 33%[20]. Koios DS Breast automatically provides an AI-based quantitative risk assessment that aligns to a BI-RADS® category with demonstrating a decrease of the benign biopsies by up to 31%.[21] To support more precise treatment planning, the multiplanar ABUS views offer surgeons a complete view of the breast in 3D with a reproducible location of pathological findings. ABUS is a great tool for treatment planning and staging due to the coronal plane access, as the full extension of the breast cancer is demonstrated in a standardized view to provide an accurate assessment of the peritumor stromal involvement and potential multiplicity of the cancer.

LOGIQ E10 Series: Detecting and characterizing breast disease, especially in women with dense tissue, can be challenging. Radiologists and sonographers need the highest quality imaging combined with productivity tools to provide definitive answers as efficiently as possible. The LOGIQ™ E10 Series helps clinicians make a real difference in the lives of patients with breast disease. The systems' cSound™ Architecture provides images of excellent detail and contrast resolution for greater diagnostic confidence, while new AI-based workflow tools help increase exam efficiency, including: Breast Productivity Package, Breast Assistant,[22] and Auto Lesion Segmentation.

SenoBright™ HD Contrast Enhanced Mammography (CEM): Performed as a follow-up to an inconclusive mammography and ultrasound, SenoBright™ HD highlights areas of unusual blood flow patterns, so practitioners can precisely see what matters. SenoBright™ HD provides advanced image quality with high specificity to help reduce false-positives and to help prevent unnecessary biopsies and surgeries.[23] The exam can be performed in less than seven minutes[24] – using the same mammography equipment, in the same room, with the same staff. Delivering clear image quality, CEM offers a high level of confidence for clinicians and patients.

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[15] IPSOS Patient Satisfaction Study sponsored by GE Healthcare, conducted with 315 patients across 2 sites in Europe, out of which 160 were offered the patient-assisted compression option, February 2017
[16] FDA PMA P110006 summary of safety and effectiveness
[17] Blumen, et al. Comparison of treatment costs for breast cancer by tumor stage, and type of service.
[18] Sparano, JA, et al. N Engl J Med 2018; 379:111-121
[19] Performance and Reading Time of Automated Breast US with or without Computer-aided Detection. Read More: https://pubs.rsna.org/doi/10.1148/radiol.2019181816.
[20] Interpretation Time Using a Concurrent-Read Computer-Aided Detection System for Automated Breast Ultrasound in Breast Cancer Screening of Women with Dense Breast Tissue (Yulei Jiang) Read More: https://www.ajronline.org/doi/10.2214/AJR.18.19516.
[21] Mango et al. Should We Ignore, Follow, or Biopsy? Impact of Artificial Intelligence Decision Support on Breast Ultrasound Lesion Assessment. AJR, June 2020: 214: 1145-1452.
[22] Not available in all regions.
[23] 510(k) K103485
[24] Daniaux et al. Arch Gynecol Obstet , 2015

Breast Biopsy Solutions: If medical indications recommend pathology, **Pristina Serena™ 3D Biopsy** transforms a Senographe Pristina screening room into an interventional suite in just two minutes with the dedicated add-on biopsy kit without requiring a long and mechanical needle installation. Clinicians now have the option of accessing the breast with the newly designed "side approach" to access a larger working space for ease of patient positioning, reducing needle visibility to help ease patient anxiety and allow best access to lesions close to the breast support. GE Healthcare also offers the industry's first contrast-guided biopsy solution **Serena Bright™ Contrast-Guided Biopsy** designed to biopsy lesions that are otherwise not clearly identifiable. The technology, which received U.S. Food and Drug Administration 510(k) clearance in May 2020, allows patients to have their breast biopsy exams with contrast guidance using the same mammography equipment, in the same room, and with the same staff as the screening or diagnostic mammogram.

ProFound AI™ 3.0: ProFound AI™ from iCAD for Senographe Pristina runs on an AI based algorithm trained to detect malignant soft tissue densities and calcifications. The algorithm's confidence that a detection or case is malignant is scored on a 0 to 100 percent scale. A higher score indicates a higher level of confidence in the malignancy of the detection or case. These Certainty of Finding and Case Scores serve as a guide to help interpreting radiologists determine if a suspicious finding or case needs further workup. Profound AI can reduce reading time by an average of 52.7%, increases sensitivity by an average of 8%, and increases specificity by an average of 6.9%.[25]

Cerianna™ (fluoroestradiol F18) Injection: Understanding estrogen receptors (ER) discordance in recurrent or metastatic breast cancer (MBC) enables clinicians to better adapt the treatment strategy of patients. Biopsy may not always be feasible in metastatic disease where the breast cancer has spread to distant organs and multiple sites[26][27][28][29][30][31][32][33]. The only imaging agent that detects whole-body ER+ lesions in MBC is Cerianna, a first-of-its-kind radioactive diagnostic agent approved in May 2020, which is indicated for use with positron emission tomography (PET) imaging for the detection of ER+ lesions as an adjunct to biopsy in patients with recurrent or metastatic breast cancer[34].

[25] iCAD labelling and user manual, DTM160 rev C. Reading times may vary based on the specific functionality of the viewing application used for interpretation

[26] Kurland BF, Wiggins JR, Coche A, Fontan C, Bouvet Y, Webner P, et al. Whole-body characterization of estrogen receptor status in metastatic breast cancer with 16α-18F-fluoro-17β-estradiol positron emission tomography: meta-analysis and recommendations for integration into clinical applications. Oncologist. 2020;25(10):835-844.

[27] Yang Z, Sun Y, Zhang Y, Xue J, Wang M, Shi W, et al. Can fluorine-18 fluoroestradiol positron emission tomography-computed tomography demonstrate the heterogeneity of breast cancer in vivo? Clin Breast Cancer. 2013;13(5):359-363.

[28] Currin E, Peterson LM, Schubert EK, Link JM, Krohn KA, Livingston RB, 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.

[29] Chae SY, Ahn SH, Kim S-B, Han S, Lee SH, Oh SJ, et al. Diagnostic accuracy and safety of 16α-[18F]fluoro-17β-oestradiol PET-CT for the assessment of oestrogen receptor status in recurrent or metastatic lesions in patients with breast cancer: a prospective cohort study. Lancet Oncol. 2019;20(4):546-555.

[30] Amir E, Miller N, Geddie W, Freedman O, Kassam F, Simmons C, et al. Prospective study evaluating the impact of tissue confirmation of metastatic disease in patients with breast cancer. J Clin Oncol. 2012;30(6):587-592.

[31] Sundararajan L, Linden HM, Link JM, Krohn KA, Mankoff DA. 18F-fluoroestradiol. Semin Nucl Med. 2007;37(6):470-476.

[32] Linden HM, Stekhova SA, Link JM, Gralow JR, Livingston RB, Ellis GK, et al. Quantitative fluoroestradiol positron emission tomography imaging predicts response to endocrine treatment in breast cancer. J Clin Oncol. 2006;24(18):2793-2799.

[33] Cardoso F, Fallowfield L, Costa A, Castiglione M, Senkus E, ESMO Guideline—Working Group. Locally recurrent or metastatic breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2011;22 Suppl 6:vi25-30.

[34] Cerianna full prescribing information accessible here.

Lunar iDXA with enCORE v18 software: Cancer patients are at risk for reduced bone density following treatment. As part of the follow-up after breast cancer treatment, DXA exams can be performed. Advanced clinical applications like DXAVision™ provide bone mineral density and body composition in one easy, unified workflow, resulting in a DXA scan that is up to 40% faster than a traditional Total Body scan.[35] Combined with TBS integration, and streamlined reporting with easier style sheets and formulas, enCORE v18 helps deliver more efficient workflows and ease the burden on technologists while streamlining patient throughput.

The team will also be offering the following programming in the GE Innovation Theater during #RSNA22:

A review of all breast imaging techniques (November 27, 2022 from 11:25 am - 11:45 am CST): Join us to learn how recommending breast imaging techniques can lead to more individualized screening.

Transformative breast care in the safety net setting (November 27, 2022 from 12:00 pm - 12:20 pm CST): Join us to learn more about providing high quality care in the safety net setting for patients from underserved backgrounds.

A multifaceted approach to fostering screening compliance from leading breast cancer organizations, patient advocates and a nurse navigator (November 29, 2022 at 11:25 a.m. CST): Join us for a panel discussion with experts from across the industry - including Cati Stone, Susan G. Komen Vice President of Community Health & Survivor; Dr. Corrine Ellsworth-Beaumont MFA, PhD, Founder of Know Your Lemons (virtual); Asha Miller, Patient Veteran and Influencer; and Diane Lack, Nurse Navigator - One-Stop Clinic™ for breast, St. Luke's University Health Network as well as members of the GE Healthcare team. The panel will examine a multifaceted approach to fostering breast screening with patients and guide you through the ins and outs of getting patients to comply with regular screenings.

Keynote: Patient access to imaging across the care journey (November 29, 2022 from 10:15am – 10:35am CST): Join us to focus on a critical topic of patient access. We believe more patients need greater access to imaging. Imaging has transformed the way medicine has practiced, from eliminating exploratory surgery, to advancing the way disease is diagnosed, treated and monitored. Greater access means providing care where the patient seeks care and throughout the patient care journey.

CEM Lexicon: toward standardization of reporting in contrast mammography (November 30, 2022 from 11:25am – 11:45 am CST): Join us to learn how to report contrast-enhanced mammography exams with the new BIRADS lexicon.

Come visit the GE Healthcare booth in the North Hall (#7324) and One-Stop Clinic™ Experience for Breast (North Hall #8349) or join us at innovation.gehealthcare.com.

Additionally, GE Healthcare's Education Room focusing on Ultrasound & Breast Care Pathway Solutions offers 22 sessions over 4 days. Click here for more information.

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[35] Data on file with GE Healthcare, April 2019.

GE Healthcare at RSNA 2022
Mammography and Breast Care
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