GE Healthcare Receives FDA Clearance of the Industry's First Contrast-Enhanced Mammography Solution for Biopsy

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Chicago, Illinois – June 9, 2020 – To help empower clinicians and patients in their fight against breast cancer, GE Healthcare today announced the Food and Drug Administration's 510(k) clearance of Pristina Serena Bright™*, the healthcare industry's first contrast-enhanced mammography solution for biopsy.

The clearance comes at a time when women's health clinics worldwide begin to reopen and are managing new protocols to help reduce staff and patient exposure to COVID-19. In the United States alone, breast cancer screenings experienced more than a 90% decline due to the pandemic.[1]

Accordingly, the Society of Breast Imaging has recommended providers consider the use of abbreviated breast procedures to reduce the time a patient is in the clinic and reduce staff to only essential employees.[2]

With Pristina Serena Bright, breast biopsy exams can now be done with the same mammography equipment, with the same staff, and in the same room as the screening or diagnostic mammogram. Previously, for lesions not seen on mammography or ultrasound, contrast-enhanced biopsy was typically performed with breast MRI. When compared to MRI-biopsy guided therapy, the potential benefits of Contrast Enhanced Spectral Mammography (CESM) biopsy include shortened procedure time, improved patient comfort, and reduced cost for patients.

"The waiting list for MRI-guided biopsy can be as long as several weeks. With CESM guided biopsies, we can schedule patients in less than one week after their initial CESM," said Dr. Rodrigo Alcantara, Head of Breast Imaging Section at Hospital del Mar in Spain. "This new mammography-guided biopsy techniques allows for a comfortable experience and provides women with answers quickly."

Key to this technology's application is GE Healthcare's SenoBright™ HD CESM, which allows clinicians to perform an entire breast exam in typically less than seven minutes with the images available immediately for a radiologist to review.[3] By highlighting areas of unusual blood flow to help localize lesions that need to be biopsied, CESM biopsy – Serena Bright™ – can help improve radiologists' diagnostic confidence.

"Now more than ever, it is critical we put the comfort of patients first and get them answers as fast as possible. We are proud to announce this FDA clearance during a time our customers need this type of innovation the most," said Agnes Berzsenyi, President and CEO of Women's Health at GE Healthcare. "We look forward to bringing this technology to the market in the upcoming months and hope it can help improve breast cancer outcomes for women during this time of uncertainty."

**Not yet commercially available.*

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About GE Healthcare:

GE Healthcare is the $16.7 billion healthcare business of GE (NYSE: GE). As a leading global medical technology 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 50,000 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.

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Media Contact:

Kate Rodgers

Katlynn.rodgers@ge.com

+1 617-872-1214

[1] Accessed on May 12, 2020: https://ehrn.org/wp-content/uploads/Preventive-Cancer-Screenings-during-COVID-19-Pandemic.pdf

[2] Accessed on May 13, 2020: https://www.sbi-online.org/RESOURCES/COVID-19Resources.aspx

[3] Daniauxet al. Arch Gynecol Obstet , 2015