Koios Medical Receives Health Canada Approval for Smart Ultrasound® AI Software for Breast Cancer Detection.

Smart Ultrasound software available in the US, across Europe, UK, the Middle East and South America is now available in Canada for improved diagnostic accuracy.

NEW YORK, USA, November 15, 2021 /EINPresswire.com/ -- Koios Medical, a fast-growing developer of artificial intelligence-based software for physicians announced it has received Health Canada approval as a Class III medical device for its flagship Koios DS Breast decision support Smart Ultrasound® software for accurately interpreting breast ultrasound examinations. Available commercially in the US since 2018 and across the EU, UK, Middle East, and South America since earlier 2021. Physicians using computer vision software consistently improve early cancer detection rates while simultaneously reducing common and costly false positives, benign biopsy procedures, effectively elevating the overall quality of care provided to patients.

“Health Canada’s approval of Koios DS Breast for early breast cancer detection is an amazing milestone, a leap forward in the battle against this deadly disease and a major advancement in care for the women and men of Canada” says Koios Medical CEO, Chad McClennan who continued, “Health Canada advances its commitment to innovation with this approval and soon through Canadian physicians using the AI software platform to support these critical, often live-saving diagnostic decisions.”

Koios Medical AI software (or “Smart Ultrasound”) for cancer detection is deployed at a rapidly growing number hospital systems, academic medical centers and imaging centers in the US, Europe, the Middle East, and South America. Health Canada's approval now makes access to this innovative software commercially available immediately across all ten Canadian provinces. Koios Smart Ultrasound is proven to accurately interpret images acquired from all major ultrasound hardware vendors, compatible with most major PACS system workstations and available directly on GE's LOGIQ E10 ultrasound scanner and within the GE Invenia ABUS 2.0 automated whole breast ultrasound system.

One out of every eight women is expected to contract breast cancer over the course of her

lifetime making breast cancer the leading cancer diagnosis in women worldwide. The earliest possible detection is critical to increased survival rates. Use of the Koios AI software dramatically expands patient access to the highest possible quality of care, helps bridge the health equity gap using software to improve clinical accuracy and early diagnosis. Research studies demonstrate the use of Koios DS Breast software elevates clinical accuracy for physicians across all experience levels.

Koios DS Breast AI software was "trained" on over half a million ultrasound images of both malignant and benign breast lesions sourced from over thirty institutions around the world. The system generates a likelihood of malignancy result aligned to both the American College of Radiology's BI-RADS rating schema and the European rating systems to both streamline workflow and ensure a proper treatment pathway.

Despite advances in mammography technology, ultrasound remains standard of care for the more than 40% of women around the world with dense breast tissue. Both cancer and dense tissue appear white, masking or making cancer invisible, on a mammogram requiring ultrasound or MRI as the recommended supplemental imaging modalities to accurately diagnose abnormalities. Computer vision, using ensembles of deep learning algorithms, can be used to analyze ultrasound exams and holds tremendous promise for reducing cancer mortality worldwide through improved diagnostic accuracy that also eliminates avoidable biopsy procedures of benign tissue. Studies have shown Smart Ultrasound to reduce false positive biopsy rates by more than 30% while improving cancer detection as much as 6%.

Machine generated results support decision-making in real-time and can be exported directly into a patient's medical record reducing errors and saving precious time. Koios Medical is currently preparing a version of software for thyroid cancer diagnosis via ultrasound image analysis and expects to add thyroid cancer detection and diagnosis as an indication to the software platform in 2022.

"Koios DS Breast brings a proven AI solution to the Canadian healthcare market for improved diagnostic accuracy combined with the speed physicians demand, especially during these unprecedented times when workloads and stress levels have reached heights never seen before. We are committed to helping improve patient care, control costs, and, most importantly, save lives. Our Canadian physician partners have aligned incentives we believe will help accelerate adoption through their commitment to value and quality care. We look forward to celebrating results with physicians and patients in Canada just as we are experiencing daily in the US and across other parts of the globe," says Koios Medical CEO Chad McClennan.

About Koios Medical:
Koios Medical develops medical software to assist physicians interpreting ultrasound images and applies deep machine learning methods to the process of reaching an accurate diagnosis. The Koios DS platform uses advanced AI algorithms to assist in the early detection of disease while reducing recommendations for biopsy of benign tissue. Patented technology saves physicians

time, helps improve patient outcomes, and reduces healthcare costs. Koios DS (decision support) is presently focused on the breast and thyroid cancer diagnosis market. Women with dense breast tissue (over 40% in the US) often require an alternative to mammography for diagnosis. Ultrasound is a widely available and effective alternative to mammography using no ionizing radiation and is a standard of care for breast cancer diagnosis. To learn more contact Koios Medical at: info@koiosmedical.com

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