DermaSensor, Inc Announces Positive Results From Melanoma Clinical Validation Study of Skin Cancer Detection Device

DermaSensor's optical spectroscopy and artificial intelligence technology demonstrated a 96% melanoma detection rate and a Negative Predictive Value of 98%.

The DermaSensor device is an affordable, handheld device that uses machine learning and spectroscopy to automatically test skin lesions for potential cancer.

MIAMI, FL, U.S.A., March 29, 2022 /EINPresswire.com/ -- DermaSensor Inc., a health technology company designing non-invasive tools to better equip primary care physicians (PCPs) to detect skin cancer, today announces the podium presentation and publication of the DERM-ASSESS III study results at the American Academy of Dermatology (AAD) Annual Meeting in Boston. For the study's primary endpoints, the device was found to have a sensitivity of 95.5% for melanoma and 90.9% across all melanomas and highly atypical melanocytic nevi. Melanoma is expected to be the second most common cancer by 2040 (ref. 1); however, 99% of melanomas are curable if detected early (ref. 2).

The DermaSensor device and its spectroscopy technology, comprised of Elastic Scattering Spectroscopy (ESS) and artificial intelligence (AI), was awarded Breakthrough Device Designation by the FDA in 2021. This handheld device is designed to evaluate lesions at the point of care for lesions suggestive of skin cancer by taking five painless, non-invasive ~1mm optical tissue samples of the lesion, automatically assessing cellular and subcellular characteristics to determine if there may be malignant features. This device may help clinicians avoid unnecessary referrals and biopsies and may help detect skin cancers earlier to benefit patients, physicians, and payers.

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> *Dr. Jane Grant-Kels, University of Connecticut School of Medicine*

"I was excited to be a Principal Investigator in this study and to now present our findings at the American Academy of Dermatology annual meeting," stated Dr. Rebecca Hartman, a dermatologist at Dana-Farber Brigham Cancer Institute and Assistant Professor of Dermatology at Harvard Medical School. "It's important to seek out ways to improve melanoma detection by clinicians, especially those with varying experience in evaluating potential skin cancers. We know how critical it is to diagnose melanoma early, as early-stage disease has an excellent prognosis, but later-stage disease carries considerable risks of morbidity and mortality."

DERM-ASSESS III was a blinded, global, prospective study performed at 10 dermatology study centers. Patients with lesions clinically suspicious for melanoma were enrolled and each lesion was evaluated by the dermatologist investigator and also using the device. Biopsy was performed in accordance with the dermatologists' standard of care with dermatopathology consensus review. 328 patients (518 lesions) were enrolled with an average age of 62 and the average lesion size was 6mm by 5mm. Pathology consensus results confirmed 113 malignant and highly atypical lesions. The test's sensitivity for melanoma detection was 95.5% and was 90.9% including highly atypical nevi. Its Negative Predictive Value (NPV) for melanoma was 98.1%. The study investigators' diagnostic sensitivity using their standard of care (i.e. dermoscopy) without DermaSensor was 90.9% for melanoma and 71.6% for melanoma including highly atypical nevi. These results suggest that the use of DermaSensor could assist dermatologists in detecting high-risk lesions and even more so, could benefit PCPs clinical management of potentially cancerous lesions since literature shows that PCPs have a lower sensitivity for detecting skin cancer than dermatologists (ref. 3).

"Currently there are no validated, FDA-approved image or optical-based tools available that provide any kind of skin cancer assessment to support physicians' detection and management of suspicious lesions," says Dr. Jane Grant-Kels, Professor of Dermatology, Pathology and Pediatrics and founding Chair Emeritus of the Department of Dermatology at the University of Connecticut School of Medicine and medical advisor to DermaSensor. "This study's clinical results are a home run. Such a significant melanoma study also adds important additional clinical validation to the DermaSensor spectroscopy technology. I hope the device will soon become the first such non-invasive, clinically-validated skin cancer tool that is FDA cleared and available, so that physicians in the U.S. have access to this wonderful and easy-to-use technology like they already do abroad."

DermaSensor Inc. is a health technology company designing non-invasive tools to better equip

primary care providers for skin cancer detection. The DermaSensor device is an affordable, handheld device that uses machine learning and spectroscopy to automatically test skin lesions for potential cancer. DermaSensor's mission is to improve outcomes and save on healthcare costs by providing broad access to effective skin cancer checks since most Americans do not receive an annual skin exam. The DermaSensor device is currently CE Marked and is registered and available for sale in Australia and New Zealand; it is not currently cleared and not available for sale in the U.S.

References:

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2. The Skin Cancer Foundation. (2022, March 27). https://www.skincancer.org/.
3. Chen, S. C. et al. (2006). Journal of general internal medicine, 21(7), 678–682. https://doi.org/10.1111/j.1525-1497.2006.00462.

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