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IR-MED's AI-Powered Infra-Red Spectrographic Decision Support System PressureSafe Device Demonstrates High Efficacy in Detecting Pressure Injuries with 96% Accuracy: Potential to Set a New Standard of Care

- ***IR-MED to file for FDA approval Q4 2023 with U.S. market launch expected in H1 2024***
- ***2.5 million patients develop pressure injuries and 60,000 die annually as a direct result; $26.8 billion is spent each year on the prevention and treatment of pressure injuries***

Rosh Pina, Israel, July 17, 2023 (GLOBE NEWSWIRE) -- IR-MED Inc., ("IR-MED" or the "Company") (OTCQB:IRME), developer of a noninvasive AI-driven Infra-Red spectrographic analysis technology platform to address significant healthcare needs, announced today topline interim results from a clinical study of PressureSafe, a noninvasive handheld optical monitoring device that supports early detection of pressure injuries (PI) to the skin and underlying tissue.

PressureSafe demonstrated very high efficacy in noninvasively detecting the presence and absence of pressure injuries below the skin's surface. Sensitivity was 96% indicating PressureSafe accurately detected the presence of a pressure injury in 96% of cases, while specificity was 91% showing PressureSafe correctly determined no wound was present in 91% of cases. The study was conducted at two medical centers owned by Clalit, the world's second largest health maintenance organization (HMO) and the largest in Israel, Beit Rivka Hospital and Rabin Medical Center both in Petah Tikva, where 370 PressureSafe scans were performed on 25 patients who had Stage 1 pressure injuries or deep tissue injuries. No device related safety issues were reported in the total of 44 patients evaluated for safety.

Pressure injuries can occur when a patient must stay in a wheelchair or bed and isn't able to move. Currently, visual inspection is used to detect and classify pressure injuries according to depth, width, degree of tissue loss, and presence of granulated tissue.

"These data confirm that PressureSafe can augment visual inspection with very high accuracy while bringing the added benefits of automated cloud-based digital storage of scan results, saving time and contributing to the healthcare provider's data-driven decision making. Moreover, because PressureSafe is detecting biomarkers below the skin's surface,

it can be more effective at sensing pressure injuries that are not yet visible to the human eye, leading to better outcomes for patients, especially those with darker skin tones," stated IR-MED's Chief Science Officer, Dr. Yaniv Cohen. "In the near future, we plan to conduct additional studies in the U.S."

IR-MED's Executive Chairman and Interim CEO Oded Bashan added, "We believe PressureSafe can become the new standard of care in the detection of pressure injuries, and we are very pleased to share this data as we plan to file for U.S. FDA approval and subsequent market launch following regulatory clearance. We believe that the healthcare economics benefits PressureSafe offers combined with the improvement in patient outcomes is a powerful combination for rapid market adoption."

PressureSafe is a handheld device to support early detection of pressure injuries to the skin and underlying tissue, regardless of skin tone. $26.8 billion is spent each year to prevent and treat pressure injuries that result from long-term pressure on hard surfaces such as wheelchairs and beds.

About IR-MED

IR-MED Inc., is developing a noninvasive spectrographic analysis technology platform, allowing healthcare professions to detect, measure and monitor, in real time, different molecules in the blood, in human tissue, and in body fluids without invasive procedures. PressureSafe, the first product under development, is a handheld optical monitoring device that is being developed to support early detection of pressure injuries (PI) to the skin and underlying tissue, regardless of skin tone as it calibrates personally to each patient's skin.

IR-MED's technology is being developed to allow accurate readings of biomarkers in a non-invasive method, that may provide caregiver the optimal decision support-system in cases where uncertainties disturb physicians in their decision processes.

IR-MED holds patents protecting its technology and innovations in the noninvasive tissue analysis, and in the modeling and analysis of subcutaneous tissue.

PressureSafe is currently undergoing usability studies at multiple medical centers. It is not yet available for commercial use.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities and Israeli securities laws. Statements that are not statements of historical fact may be deemed to be forward-looking statements. For example, the Company is using forward-looking statements in this press release when it discusses its expectancy to file for FDA approval in the fourth quarter of 2023, that the U.S. market launch is expected in the first half of 2024, that it plans to conduct additional studies in the U.S. in the near future and the belief that the healthcare economic benefits PressureSafe offers, combined with the improvement in patient outcomes, is a powerful combination for rapid market adoption.. Without limiting the generality of the foregoing, words such as "plan," "project," "potential," "seek," "may," "will," "expect," "believe," "anticipate," "intend," "could," "estimate" or "continue" are intended to identify forward-looking statements. Readers are cautioned that

certain important factors may affect the Company's actual results and could cause such results to differ materially from any forward-looking statements that may be made in this press release. Statements relating to the future performance of IR-Med are subject to many factors including, but not limited to, the sufficiency or working capital and our ability to raise the capital needed to fund our development efforts, completion of the development and design of PressureSafe device, results of preliminary clinical/useability studies and trials and confirmation by subsequent studies, replication of initial favorable product study results, timing of product development, FDA approval/clearance of products in development, customer acceptance of our products in the market, the introduction of competitive products, the impact of any product liability or other adverse litigation, commercialization and technological difficulties. The forward-looking statements contained or implied in this press release are subject to other risks and uncertainties, many of which are beyond the control of the Company, including those set forth in the Risk Factors section of the Company's Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 29, 2023 which is available on the SEC's website, www.sec.gov. The Company undertakes no obligation to update these statements for revisions or changes after the date of this release, except as required by law.

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Attachment

- IR-Med, Inc.

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IR-MED’s PressureSafe Non-Invasive Device