

**FOR IMMEDIATE RELEASE:**

**SANUWAVE, Inc. Announces 100<sup>th</sup> Patient Has Enrolled in the dermaPACE Device Investigation Device Exemption (IDE) Clinical Trial**

**Alpharetta, GA, March 1, 2009** – Patient enrollment has passed its mid-point for the Investigation Device Exemption (IDE) clinical trial evaluating Pulsed Acoustic Cellular Expression (PACE™) Technology, using the dermaPACE™ device, for the treatment of diabetic ulcers of the foot. SANUWAVE, Inc., the provider and developer of Pulsed Acoustic Cellular Expression (PACE) technology, has watched as enrollment accelerated over the last few months of 2008 after receiving approval from the FDA to initiate a multi-center, prospective, randomized clinical trial utilizing its novel dermaPACE device in late 2007.

The first 100 patients' procedures were performed as part of the national U.S. dermaPACE trial, which seeks to enroll a total of 180 patients through multiple sites across the U.S. to evaluate the efficacy and safety of the dermaPACE device. Additional international sites in the United Kingdom and Germany joined the trial at the beginning of 2009. Patients in the active study arm receive 4 treatments over a 2 week period with the dermaPACE device which exposes the ulcer to pulsed acoustic energy waves.

Patient test results from the independent multicenter study are completely blind. Therefore, until the trial is completed and data is unlocked, information concerning trial results will remain unknown to all parties, including SANUWAVE, its independent Contract Research Organization ("CRO") and the participating sites.

"We're very excited to have the opportunity to try this innovative technique with our patients," said Alexander Reyzelman, DPM, who performed the first procedure conducted during the trial.

Earlier studies have suggested that PACE Technology may offer an improved standard of care that may shorten a lengthy conservative therapy healing process and may make later operative measures, such as amputation, unnecessary. Given that current conservative therapy or standard of care may not be effective for all patients, PACE may be a preferable, lower risk alternative. PACE has been reported to reduce wound size and increase the rate of wound closure in several peer reviewed publications.

The dermaPACE device received European CE Mark approval in March 2007 for the treatment of acute and chronic defects of the skin and subcutaneous soft tissues e.g. post-operative wound healing defects, post-traumatic wounds, deep partial thickness burns, decubitus ulcers, diabetic ulcers, and arterial ulcers. Early European results are very encouraging. Jeschke and Petschke et al, from the University of Innsbruck, presented the beneficial effects of dermaPACE treatments in diabetic patients suffering from chronic foot and leg ulcers at the Wound Care Congress in Houston, Texas, USA in October 2007. During this study, the doctors reported that the average reduction in wound size was from 5.1+/-5.5cm<sup>2</sup> to 0.4+/-0.5cm<sup>2</sup>. All patients experienced improvement, and 75% of patients achieved complete closure within 62 days. Dr. Kristien Van Acker et al of Saint Joseph's Clinic in Bornem, Belgium also reported a 75% efficacy rate using the dermaPACE in the treatment of diabetic foot ulcers during the European Wound Management Association (EWMA) meeting in Lisbon, Portugal in May 2008. Since these small studies can only hint at

clinical efficacy, it is the intent of this large, blinded study to determine if the results can be reproduced in a statistically valid manner.

“Our goal is to restore function and quality of life to diabetic patients who have been stricken with this debilitating condition by liberating them of the burdens of chronic wound care and preventing amputation,” said Christopher M. Cashman, SANUWAVE President and CEO. “As our clinical trial rounds the mid-enrollment point, we know that we are getting closer to giving the healthcare community a real solution to a demanding medical problem.”

#### **About SANUWAVE, Inc.**

SANUWAVE, Inc., is a global medical technology company focused on the development and utilization of Extracorporeal Shock Wave Technology (ESWT) and Pulsed Acoustic Cellular Expression (PACE) technology for orthopedic, advanced wound care, cardiovascular and neurological conditions. Headquartered in Alpharetta, GA with international offices in Lengwil, Switzerland and Tokyo, Japan, SANUWAVE designs, manufactures, markets, and services its industry leading products worldwide. The company's dermaPACE has the European Community's CE Mark approval for use in acute and chronic defects of the skin and subcutaneous soft tissue. SANUWAVE's veterinary business promotes VersaTron® ESWT for equine applications and VersaTron 4 Paws® for use on small animal maladies such as degenerative joint disease. SANUWAVE is undertaking extensive research into the biological mechanisms and cellular effects of ESWT and PACE, to include anti-inflammatory response, angiogenesis promotion, and bactericidal capabilities.

For more information, please visit the SANUWAVE website at [www.sanuwave.com](http://www.sanuwave.com).

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This press release contains forward-looking statements that involve risks and uncertainties. These include statements regarding the Company's growth and expansion plans. Such statements are based on management's current expectations and are subject to a number of uncertainties and risks that could cause actual results to differ materially from those described in the forward-looking statements.

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