



Healing today. Curing tomorrow.

SANUWAVE Health, Inc.
Barry Jenkins, CFO
Bernie Laurel, VP of Sales and Marketing
678-578-0103
investorrelations@sanuwave.com

Lippert/Heilshorn & Associates
Anne Marie Fields (Investors)
212-838-3777
afields@lhai.com
Mackenzie Mills (Media)
212-838-3777
mmills@lhai.com

FOR IMMEDIATE RELEASE

SANUWAVE DERMAPACE TECHNOLOGY SHOWN SUPERIOR TO HYPERBARIC OXYGEN THERAPY IN INCREASING ANGIOGENIC AND TISSUE REGENERATIVE MOLECULAR CHANGES IN DIABETIC FOOT ULCERS

ALPHARETTA, GA, October 12, 2011 – SANUWAVE Health, Inc. (OTCBB: SNWV), an emerging medical technology company focused on the development and commercialization of noninvasive, biological response activating devices in regenerative medicine, today announced the publication of research that investigated the molecular changes of dermaPACE[®] extracorporeal shock wave technology (ESWT) compared with hyperbaric oxygen therapy (HBOT) in diabetic foot ulcers. The study, entitled “*Molecular Changes in Diabetic Foot Ulcers*,” by Ching-Jen Wang, M.D. of the Department of Orthopedic Surgery, Kaohsiung Chang Gung Memorial Hospital and Chang Gung University College of Medicine in Kaohsiung, Taiwan, appeared in the online edition of the European peer-reviewed journal *Diabetes Research and Clinical Practice* as an ePublication ahead of print.

The abstract of the publication can be viewed online at the *Diabetes Research and Clinical Practice* website: <http://www.sciencedirect.com/science/article/pii/S0168822711003366>

Summary of Key Study Findings

- ▶ dermaPACE showed statistically significant increases in angiogenic and tissue regenerative molecular changes over HBOT in diabetic foot ulcers.
- ▶ dermaPACE demonstrated significant increases in angiogenesis (vWF, VEGF and eNOS) and cell proliferation (PCNA and EGF) and decreases in cell apoptosis (TUNEL), leading to tissue regeneration and wound repair (p<0.05), whereas the molecular changes after HBOT were not statistically significant.
- ▶ The results help explain why dermaPACE was significantly more successful than HBOT in healing complex diabetic foot ulcers in a previously reported study involving the same patient group.

Christopher M. Cashman, President and CEO of SANUWAVE, said, “The proangiogenic and tissue regenerative mechanisms of action of dermaPACE, and extracorporeal shock wave technology in general, are well documented in the peer-reviewed literature. This research by Dr. Wang and his colleagues is the first time that the molecular changes induced by dermaPACE have been compared with those of hyperbaric oxygen therapy, and we are naturally pleased with dermaPACE’s superior results. These results provide considerable clinical insight into why, in a previously reported study involving the same patient population, dermaPACE healed nearly three times as many ulcers as HBOT.”

The study consisted of 39 patients (44 ulcers) in the ESWT group and 38 patients (40 ulcers) in the HBOT group, with similar demographic characteristics. The ESWT group received dermaPACE procedures twice per week for a total of six procedures over three weeks. The HBOT group received hyperbaric oxygen therapy daily for a total of 20 treatments, each lasting 90 minutes. Biopsies were performed from the periphery of the ulcer before and after treatment. The specimens were immunostained, and the positive immuno-activities of vWF, VEGF, eNOS, PCNA, EGF and TUNEL expressions were examined and quantified microscopically.

The results showed that dermaPACE significantly increased all studied angiogenic and tissue regenerative molecular changes in diabetic foot ulcers, while none was increased significantly for HBOT therapy. Following dermaPACE treatment, significant increases in vWF, VEGF, eNOS, PCNA and EGF expressions, plus a decrease in TUNEL expression, were demonstrated ($p < 0.05$). These molecular changes play a crucial role in wound healing by converting a chronic wound into an acute wound, thereby helping the body to reinitiate the complex, multi-factorial healing cascade.

Dr. Wang commented, "At a molecular level, failure of wound healing may result either from deficient supply or functional inhibition of growth factors such as those investigated during this study. The results of the current study suggest that the mechanism of action of ESWT with dermaPACE improves wound healing by increasing angiogenesis and cell activity in the wound environment, normalizing the rate of programmed cell death (apoptosis) and making positive changes to growth factor and cytokine levels. These findings are supported by other studies that ESWT enhanced skin flap survival and diabetic wound healing by increasing angiogenesis and topical blood perfusion in animals."

Mr. Cashman concluded, "Our recently completed pivotal Phase III clinical trial investigating dermaPACE to heal diabetic foot ulcers enrolled patients having Wagner grade I and II diabetic foot ulcers. Dr. Wang's study enrolled patients with predominately Wagner grade III and IV ulcers that were at least three months in duration. These were very sick patients with severe clinical complications involving their diabetic foot ulcers, such as abscesses, bone infections and even localized gangrene. Nevertheless, dermaPACE was able to significantly induce the biologic effects known to ultimately contribute to wound healing, whereas hyperbaric oxygen therapy did not."

About PACE®

PACE, defined as Pulsed Acoustic Cellular Expression, delivers high-energy acoustic pressure waves in the shock wave spectrum to produce compressive and tensile stresses on cells and tissue structures to promote angiogenic and positive inflammatory responses, and quickly initiate the healing cascade. This results in revascularization and microcirculatory improvement, including an increase in arterial vessel diameter (arteriogenesis), the production of angiogenic growth factors, enhanced new blood vessel formation (angiogenesis), and the subsequent regeneration of tissue such as skin, musculoskeletal and vascular structures. PACE treatment triggers the initiation of an accelerated inflammatory response that speeds wounds into the proliferation phase of healing and subsequently returns a chronic condition to an acute condition, to help reinitiate the body's own healing response.

About SANUWAVE Health, Inc.

SANUWAVE Health, Inc. (www.sanuwave.com) is an emerging regenerative medicine company focused on the development and commercialization of noninvasive, biological response activating devices for the repair and regeneration of tissue, musculoskeletal and vascular structures. SANUWAVE's portfolio of products and product candidates activate biologic signaling and angiogenic responses, including new vascularization and microcirculatory improvement, helping to restore the body's normal healing processes and regeneration. SANUWAVE intends to apply its PACE technology in wound healing, orthopedic/spine, plastic/cosmetic and cardiac conditions. Its lead product candidate for the global wound care market, dermaPACE, is CE marked for treatment of the skin and subcutaneous soft tissue and recently completed its highly positive pivotal Phase III, Investigational Device Exemption (IDE) clinical trial in the U.S. for the treatment of diabetic foot ulcers. SANUWAVE researches, designs, manufactures, markets and services its products worldwide, and

believes it has demonstrated that its technology is safe and effective in stimulating healing in chronic conditions of the foot (plantar fasciitis) and the elbow (lateral epicondylitis) through its U.S. Class III PMA approved Ossatron[®] device, as well as stimulating bone and chronic tendonitis regeneration in the musculoskeletal environment through the utilization of its Ossatron, Evotron[™] and orthoPACE[®] devices in Europe.

Forward-Looking Statements

This press release may contain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, such as statements relating to financial results and plans for future business development activities, and are thus prospective. Forward-looking statements include all statements that are not statements of historical fact regarding intent, belief or current expectations of the Company, its directors or its officers. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, many of which are beyond the Company’s ability to control. Actual results may differ materially from those projected in the forward-looking statements. Among the key risks, assumptions and factors that may affect operating results, performance and financial condition are risks associated with the marketing of the Company’s product candidates and products, unproven pre-clinical and clinical development activities, regulatory oversight, the Company’s ability to manage its capital resource issues, competition, and the other factors discussed in detail in the Company’s periodic filings with the Securities and Exchange Commission. The Company undertakes no obligation to update any forward-looking statement.
