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FOR IMMEDIATE RELEASE

**STUDY SHOWS SANUWAVE'S DERMAPACE IS SIGNIFICANTLY MORE EFFECTIVE THAN HYPERBARIC OXYGEN THERAPY IN HEALING CHRONIC DIABETIC FOOT ULCERS**

***dermaPACE Completely Healed Nearly 3 Times More Ulcers than HBOT with Fewer Treatments and Less Treatment Time***

ALPHARETTA, GA, March 16, 2011 – SANUWAVE Health, Inc. (OTC/BB: SNWV) ([www.sanuwave.com](http://www.sanuwave.com)), an emerging medical technology company focused on the development and commercialization of non-invasive, biological response activating devices in regenerative medicine, today announced the publication of research conducted in Taiwan comparing the effectiveness of the Company's dermaPACE<sup>®</sup> device with hyperbaric oxygen therapy (HBOT) in treating chronic diabetic foot ulcers. The study, entitled "Treatment of Diabetic Foot Ulcers: A Comparative Study of Extracorporeal Shockwave Therapy and Hyperbaric Oxygen Therapy," by Wang, C.J. et al., appeared in the online edition of *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://dx.doi.org/10.1016/j.diabres.2011.01.019>.

**Summary of Key Study Findings**

- ▶ dermaPACE<sup>®</sup> demonstrated significantly improved healing compared with HBOT (p=0.003).
- ▶ After one course of treatment, dermaPACE<sup>®</sup> completely healed 24 ulcers compared with 10 ulcers for HBOT (2.4 times more). After a second course of treatment, dermaPACE<sup>®</sup> completely healed a combined 31 ulcers compared with 11 ulcers for HBOT (2.8 times more).
- ▶ After one course of treatment, a significantly greater number of ulcers treated with HBOT were unchanged in size and depth compared with ulcers treated with dermaPACE<sup>®</sup> (p<0.001).
- ▶ Perfusion (blood flow) significantly increased in the dermaPACE<sup>®</sup> group after treatment (p<0.001), while remaining statistically unchanged in the HBOT group.
- ▶ dermaPACE<sup>®</sup> required 85% fewer treatments and 97% less treatment time compared with HBOT.

This prospective, open-label, randomized study included patients with chronic, non-healing diabetic foot ulcers of at least three months duration that were predominately grade III and IV on the Wagner Ulcer Classification Scale where infection, localized pus, bone inflammation and even gangrene were present. As a result, this study included very sick patients who, absent successful medical treatment, may have been faced with surgical intervention, including limb amputation.

## **Review of Study Results**

The overall clinical results showed complete healing in 57% of the diabetic foot ulcers in the dermaPACE<sup>®</sup> group, compared with 25% in the HBOT group ( $p=0.003$ ).

A second course of treatment was offered to patients with improved but incomplete healing of their ulcers 4-6 weeks from the first treatment. The results showed complete healing of 50% of these ulcers (7 of 14) in the dermaPACE<sup>®</sup> group compared with 6% (1 of 17) in the HBOT group.

60% of ulcers treated with HBOT were unchanged in size and depth compared with only 11% of ulcers treated with dermaPACE<sup>®</sup> ( $p<0.001$ ). Eight ulcers (47%) in the HBOT group showed no clinical improvement after a second course of treatment, while only one ulcer (7%) remained unchanged in the dermaPACE<sup>®</sup> group.

It is understood that increased perfusion has a direct, positive effect on ischemic wound conditions that are often the primary cause or a contributing co-morbidity in chronic diabetic ulcers. Therefore, blood flow perfusion rates (a measure of microcirculatory activity) were assessed before and after treatment in both study groups. Perfusion rates were comparable between the two groups before treatment, but statistically significant differences were noted favoring the dermaPACE<sup>®</sup> group after treatment ( $p=0.002$ ). Perfusion increased 27% in the dermaPACE<sup>®</sup> group after treatment ( $p<0.001$ ), while perfusion remained statistically unchanged in the HBOT group.

Two pathologists blinded to the group assignment performed histological examinations on biopsy specimens that were taken from the edge of the ulcer, including intact skin. Considerably higher cell proliferation, cell concentration and cell activity – with lower cell apoptosis (disintegration) – were seen in the dermaPACE<sup>®</sup> group. The study's investigators believe that these biologic effects, combined with increased tissue perfusion, contribute to the ability of dermaPACE<sup>®</sup> to heal these clinically challenging diabetic foot ulcers.

Ching-Jen Wang, M.D., a prominent researcher in the field of shock wave therapy from Chang Gung Memorial Hospital in Kaohsiung, Taiwan, and the study's lead investigator, said, "I am impressed with the clinical findings of this study, which suggest that dermaPACE<sup>®</sup> has the ability to improve wound healing by increasing perfusion in the wound environment and normalizing the rates of cell apoptosis and tissue regeneration in chronic diabetic foot ulcers. By elevating perfusion in the wound area, the ischemic component of the chronic wound disease state is decreased immediately. HBOT is the most common adjunctive therapy in the care of chronic Grade III and IV diabetic foot ulcers today, but the results of this study show that dermaPACE<sup>®</sup> is more effective than HBOT in the treatment of these problematic ulcers."

Christopher M. Cashman, President and CEO of SANUWAVE, said, "The results from this study underscore the potential of dermaPACE<sup>®</sup>, with its proven pro-angiogenic mechanism of action, to change the clinical and economic landscape in diabetic foot ulcer healing. Since the majority of ulcers in this study were Wagner grade III and IV, dermaPACE<sup>®</sup> was shown to cause exceptional healing of very complicated, chronic wounds in patients with a high risk of requiring surgical intervention. dermaPACE<sup>®</sup> completely healed 70% of these ulcers (31 of 44), and the vast majority

healed after a single course of treatment. In the U.S. alone, diabetic foot ulcers lead to more than 80,000 limb amputations each year at a direct and indirect cost of \$20,000 to \$60,000 per patient. The potential utility of dermaPACE<sup>®</sup> to increase limb salvage rates, decrease overall healthcare costs and greatly improve patients' quality of life creates a viable clinical and economic opportunity throughout the entire healthcare value chain."

Mr. Cashman continued, "On a comparative basis with HBOT, dermaPACE<sup>®</sup> performed very well, not just by demonstrating significantly higher clinical effectiveness without systemic or local complications, but also by delivering those results through a much more efficient utilization of time and resources. To complete a single course of treatment, HBOT patients in this study underwent 40 treatments of 90 minutes each, totaling a minimum of 60 hours of direct treatment time. In contrast, dermaPACE<sup>®</sup> patients underwent only six procedures of 20 minutes each, totaling two hours. So while HBOT is a commonly used adjunctive therapy in the care of chronic diabetic foot ulcers, research such as this suggests that, in many cases, a change in clinical practice is likely to improve outcomes and reduce cost. dermaPACE<sup>®</sup> is well-positioned to provide that change."

### **Study Design**

This study was prospective and randomized, and included 39 patients (44 ulcers) in the dermaPACE<sup>®</sup> group and 38 patients (40 ulcers) in the HBOT group. The dermaPACE<sup>®</sup> group received two 20-minute procedures per week for three weeks, totaling six procedures. The HBOT group received five 90-minute treatments per week, once daily for eight weeks, totaling 40 treatments. Both groups received the same standard wound care protocol after treatment, which included offloading, wound cleansing with sterile normal saline solution and application of silver sulfadiazine cream. Evaluations included clinical assessment, a blood flow perfusion scan and histopathological examination.

Clinical assessment was comprised of visual observation and photo-documentation. A blood flow perfusion scan and biopsy were performed prior to the initiation of treatment and again at the end of the treatment protocol. Follow-up examinations were scheduled at three and six weeks, then once every three months. Patients in each group were followed for a maximum of 18 months. A second course of treatment was offered to patients with improved but incomplete healing of the diabetic foot ulcer 4-6 weeks from the first treatment.

### **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 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 proliferation phases of healing and subsequently returns a chronic condition to an acute condition to help re-initiate the body's own healing response.

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

SANUWAVE Health, Inc. ([www.sanuwave.com](http://www.sanuwave.com)) is an emerging regenerative medicine company focused on the development and commercialization of non-invasive, 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) 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 this 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.*

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