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FOR IMMEDIATE RELEASE

SANUWAVE ANNOUNCES POSITIVE TOP-LINE DATA FROM ITS PIVOTAL TRIAL INVESTIGATING THE USE OF DERMAPACE FOR THE TREATMENT OF DIABETIC FOOT ULCERS

Initial Results Clearly Demonstrate the Ability of dermaPACE to Heal Diabetic Foot Ulcers

SANUWAVE Expects to Submit Final Clinical PMA Module to FDA in Early 2011

ALPHARETTA, GA, December 15, 2010 – SANUWAVE Health, Inc. (OTC BB: SNWV) (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 positive top-line results from the Company's pivotal Phase III, Investigational Device Exemption (IDE) clinical trial comparing dermaPACE™ to sham control (non-active treatment), when both are combined with the current standard of care for the treatment of diabetic foot ulcers. Diabetic foot ulcers are an area of significant unmet medical need and represent a $2 billion market in the U.S. alone.

The design of this 206-patient, randomized, double-blind, parallel-group, sham-controlled, multi-center, 26-week clinical trial was intended to quantify the effectiveness of four 20-minute, non-invasive procedures with dermaPACE™, delivered over a 2-week period.

Study Results

Comparing wound area closure at 12 weeks, 45% of patients treated with dermaPACE™ and 26% of sham patients experienced a ≥90% closure (p=0.0182), and 66% of patients treated with dermaPACE™ and 47% of sham patients experienced a ≥70% closure (p=0.0227). Within 4 weeks following the final treatment with dermaPACE™ (6-week point), and consistently throughout the 12-week evaluation period, there was a highly significant reduction in the size of the target ulcer compared to patients randomized to receive sham (p=0.0038 at week 6, p=0.0018 at week 8, p=0.0007 at week 10, and p=0.0041 at week 12). By 12 weeks, the average percent reduction in the size of the target ulcer in patients treated with dermaPACE™ was 56%, compared to only 7% in the patients randomized to receive sham. A consistently greater proportion of patients randomized to receive sham experienced continued worsening as evidenced by an increase in the size of the ulcer from baseline, compared to patients randomized to receive dermaPACE™ treatment.

Patients treated with dermaPACE™ showed a strong positive trend in the primary endpoint of 100% wound closure. Treatment with dermaPACE™ increased the proportion of diabetic foot ulcers that closed within 12 weeks by 36%, although this result was not statistically significant. Based on the pure, controlled design of the study, which restricted investigators from closing the wound surgically, and because a ≥90% wound closure is clinically meaningful, the Company ran a composite analysis

of ≥90% wound closure that demonstrated statistical significance (p=0.0161) in favor of dermaPACE™ (51/107, 48%) compared to patients randomized to receive sham (31/99, 31%). The median wound closure exceeded 99% for the dermaPACE™ treated patients in the composite analysis. Notably, the patients treated with dermaPACE™ started, at baseline, with a 58% larger wound area than patients randomized to receive sham. Patients treated with dermaPACE™ were twice as likely to achieve 90% to 100% wound closure within 12 weeks of their initial dermaPACE™ treatment compared to patients randomized to receive sham.

Dr. Robert Galiano, a principal investigator in the dermaPACE™ study and Assistant Professor, Division of Plastic Surgery, Department of Surgery at the Northwestern University Feinberg School of Medicine said, “The overwhelming clinical utility demonstrated in this study means I can expect that at least half of my patients over a 12-week period will be either fully healed or ≥90% healed. I consider this to be clinically relevant wound closure since most will continue to full closure with a basic dressing and minimal intervention.”

Dr. Galiano continued, “The scientific mechanism activated by dermaPACE™ technology has a direct and lasting impact on wounds by immediately increasing blood perfusion and stimulating the body’s own angiogenic and positive inflammatory wound healing responses. These study results have provided the necessary clinical evidence to validate the benefits of such a mechanism when combined with proper wound care.”

Importantly, there were no serious and related adverse events associated with dermaPACE™ treatment reported during the course of the study, and no issues regarding the tolerability of the treatment. Of the patients who achieved complete wound closure at 12 weeks, the recurrence rate was only 4.5% in the dermaPACE™ group compared to 20% in the patients treated with sham.

“The pure study design we implemented was double-blind, randomized and sham-controlled to provide highly credible, unbiased evidence that dermaPACE™ alone significantly and positively impacts the wound healing process,” said Christopher M. Cashman, President and CEO of SANUWAVE.

Mr. Cashman continued, “We are confident that the positive data generated by this rigorous Phase III study demonstrates clinical relevance with statistical significance in the composite analysis of 90% or better wound closure and confirms the clinical utility of dermaPACE™ to treat diabetic foot ulcers. Analysis of the complete data set will continue for some time. A substantial amount of data, in addition to the top-line data announced today, will be included in our PMA submission, the final module of which is expected to be filed in early 2011. SANUWAVE would like to thank our principal investigators and their teams for their disciplined approach to this study and for their consistent and enthusiastic support of our technology to treat their patients who suffer from diabetic foot ulcers.”

Study Design Relevance

Unlike many other chronic wound trials conducted in this diabetic patient population, there were two important elements incorporated in the dermaPACE™ study design: double-blind (patient and principal investigator) randomization, and elimination of the option to close the target ulcer surgically or by other primary means. Maintaining the double-blind in this device trial restricted the knowledge of the treatment assignment so not to influence how a patient was treated or maintained on study and evaluated. This eliminated unintended human bias and qualifies this research as level 1 evidence, allowing the results to be accepted at face value. By not allowing the clinical investigators to surgically close the target ulcer in this study, the results provide a clear and unbiased view of the granulation and epithelialization process attributable to dermaPACE™ alone.

Medical Need

Diabetes is common, disabling and deadly. In the U.S., diabetes has reached epidemic proportions. According to the American Diabetes Association, about 24 million people (8% of the total U.S. population) have diabetes, and nearly two million new cases are diagnosed in people aged 20 years or older each year. If current trends continue, 1 in 3 Americans will develop diabetes at some point in their lifetime, and those with diabetes will lose, on average, 10-15 years of life expectancy. Importantly, up to 25% of people with diabetes will develop a diabetic foot ulcer, resulting in 3 million diabetic foot ulcers annually in the U.S. alone. More than half of all foot ulcers will become infected, thus requiring hospitalization, and 1 in 5 will require an amputation that carries a high risk of mortality.

Without question, diabetes puts tremendous economic pressure on the U.S. healthcare system. Total costs (direct and indirect) of diabetes reach $174 billion annually, and people with diagnosed diabetes have medical expenditures that are over two times higher than medical expenditures for people without diabetes. Hospitalization costs alone are $16,000 to $20,000 for a patient with a diabetic foot ulcer, and direct and indirect costs of an amputation range from $20,000 to $60,000 per patient. Advanced, cost-effective treatment modalities for diabetes and its comorbidities, including diabetic foot ulcers, are in great need, yet in short supply, globally. According to the American Diabetes Association, by the year 2025 the prevalence of diabetes is expected to rise by 72% to 324 million people worldwide.

Phase III Study Design

The dermaPACE™ pivotal Phase III trial was a prospective, randomized, double-blinded, sham-controlled, multi-center, 26-week, parallel-group study. The goal of the study was to establish superiority in diabetic foot ulcer healing rates using the dermaPACE™ treatment compared with sham control, when both are combined with the current standard of care. The standard of care includes wet-to-dry dressings and, for some patients, offloading with a walking boot. Secondary trial endpoints include time to closure, reduction in total wound surface area and volume, rate of improvement, long-term safety, and skin appearance and pain assessments. The study's primary endpoint of wound closure is defined as full skin re-epithelialization without drainage or dressing requirements confirmed at two consecutive visits. A total of 206 patients were enrolled in the trial, which was conducted at 22 sites in the U.S. and two sites in Europe including Boston Medical Center, Phoenix VA, Northwestern University in Chicago, VA Long Beach, California, The Ohio State University Medical Center in Columbus, King's College Hospital in London, Emory Orthopedics and Spine Center in Atlanta, Calvary Hospital in New York, and the North American Center for Limb Preservation in New Haven, Connecticut. The principal investigators in the study represent the multidisciplinary nature of treating chronic wounds, including specialties such as vascular surgery, plastic surgery, podiatry and general surgery.

About PACE™

PACE™, defined as Pulsed Acoustic Cellular Expression, delivers high-energy acoustic pressure waves 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, speeding wounds into proliferation phases of healing and subsequently returns a chronic condition to an acute condition to help the body's own healing response to re-initiate.

About SANUWAVE Health, Inc.

SANUWAVE Health, Inc. (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 Pulsed Acoustic Cellular Expression (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 pivotal Phase III, Investigational Device Exemption (IDE) trial in the U.S. for the treatment of diabetic foot ulcers (DFU). SANUWAVE researches, designs, manufactures, markets and services its products worldwide and believes it has already 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 recently introduced orthoPACE™, devices in Europe.

Safe Harbor Statement

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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