



Healing today. Curing tomorrow.

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FOR IMMEDIATE RELEASE

SANUWAVE ANNOUNCES POSITIVE 24-WEEK DATA FROM ITS PIVOTAL TRIAL WITH DERMAPACE FOR THE TREATMENT OF DIABETIC FOOT ULCERS

Results Clearly Demonstrate dermaPACE Safely Heals Diabetic Foot Ulcers

Conference Call with Principal Investigators Begins at 11:00 a.m. Eastern Time Today

ALPHARETTA, GA, July 12, 2011 – SANUWAVE Health, Inc. (OTC BB: SNWV), an emerging medical technology company focused on the development and commercialization of noninvasive, biological response activating devices in regenerative medicine, today announced positive 24-week data from the Company's pivotal double-blinded, randomized Phase III, Investigational Device Exemption (IDE) clinical trial comparing dermaPACE[®] with 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 annual market in the U.S. alone.

The 206-patient, randomized, double-blinded, parallel-group, sham-controlled, multicenter, 24-week pivotal clinical trial was designed to quantify the safety and effectiveness of four, 20-minute, noninvasive procedures with dermaPACE, delivered over a two-week period.

Summary of Key Study Findings

- ▶ The primary efficacy endpoint of complete wound closure reached statistical significance at 20 weeks in the Intent-to-Treat (ITT) population with 36% of dermaPACE subjects achieving complete wound closure compared with 23% of Sham-control subjects (p=0.047); in the Efficacy Evaluable (EE) population 38% of dermaPACE subjects achieved complete wound closure beginning at 20 weeks, compared with 21% of Sham-control subjects (p=0.018); at 24 weeks dermaPACE achieved 40% complete wound closure in the ITT population (p=0.054) and 41% complete wound closure in the EE population (p=0.022).
- ▶ Subjects treated with dermaPACE achieved a significant increase in the rate of complete wound closure or ≥90% wound area reduction by or at 12 weeks (p=0.016).
- ▶ Within 6 weeks following the initial dermaPACE procedure, and consistently throughout the 24-week period, dermaPACE significantly reduced the size of the target ulcer compared with subjects randomized to receive Sham-control (p<0.05).
- ▶ Of the subjects who achieved complete wound closure at 12 weeks, the recurrence rate at 24 weeks was only 4.5% in the dermaPACE group compared with 20% in the Sham-control group.
- ▶ The rate of adverse events between the two groups showed no significant difference, and no issues regarding the tolerability of dermaPACE procedures were shown.

Christopher M. Cashman, President and CEO of SANUWAVE, said, “The highly positive clinical results from this rigorous Phase III study validate the ability of dermaPACE to safely heal diabetic foot ulcers. The study showed a high degree of significance in the size reduction of ulcers treated with dermaPACE at 12 weeks, which continued to statistical significance of complete wound closure at 20 weeks.”

Mr. Cashman continued, “Equally important, dermaPACE procedures were proven to be safe, and very well tolerated, which greatly expands the clinical utility of dermaPACE by removing a potential obstacle to patient selection and enhancing widespread utilization. Finally, with only a 4.5% ulcer recurrence rate in the dermaPACE group, the study demonstrated that ulcers closed with dermaPACE showed a strong tendency to stay closed. With the high rates of morbidity and mortality associated with chronic, non-healing diabetic foot ulcers, not to mention the high cost of ongoing treatment and diminished quality of life for patients and their families, closing diabetic foot ulcers safely – and keeping them closed – is paramount. In this study, dermaPACE clearly demonstrated its ability to accomplish exactly that.”

Primary Efficacy Analysis at 12 and 24 Weeks

The prospectively defined primary efficacy endpoint was the incidence of complete wound closure at 12 weeks following initial application of dermaPACE (active or sham). Complete wound closure was defined as skin re-epithelialization without drainage or dressing requirements, confirmed over two consecutive visits, two weeks apart. In addition to the 12-week analysis, the primary efficacy endpoint was analyzed through 24 weeks.

The ITT population consisted of 206 subjects who satisfied all entry criteria to be randomized and received at least one active dermaPACE or sham-control procedure. The EE population consisted of 194 subjects who followed the protocol without significant deviations, making adjustments for those who were outside the study protocol parameters of having a diabetic foot ulcer at baseline equal to or between 1cm² and 16cm² or had a decrease in ulcer volume by more than 50% during the two-week run-in period, prior to randomization.

As previously reported, the rate of complete wound closure between dermaPACE and Sham-control at 12 weeks in the ITT population was not statistically significant at the 95% confidence level used throughout the study (p=0.363). There were 22 out of 107 (21%) dermaPACE subjects who achieved complete wound closure at 12 weeks compared with 15 out of 99 (15%) Sham-control subjects.

In addition to the originally proposed 12-week efficacy analysis, the U.S. Food and Drug Administration (FDA) expressed interest in seeing the efficacy analysis carried over the full 24 weeks of the study. In response, SANUWAVE conducted a series of secondary analyses of the primary endpoint of complete wound closure at 12 weeks and at each subsequent study visit out to 24 weeks.

The primary efficacy endpoint of complete wound closure reached statistical significance at 20 weeks in the ITT population with 39 out of 107 (36%) dermaPACE subjects achieving complete wound closure compared with 23 out of 99 (23%) Sham-control subjects (p=0.047). The rate of healing was maintained in the dermaPACE group at 24 weeks with 42 out of 107 (40%) dermaPACE subjects achieving complete wound closure compared with 26 out of 99 (26%) Sham-control subjects (p=0.054).

In the EE population, 38 out of 101 (38%) dermaPACE subjects compared with 20 out of 93 (21%) Sham-control subjects achieved complete wound closure which was significant at 20 weeks (p=0.018) and continued through 24 weeks (p=0.022).

Of the patients who achieved complete wound closure at 12 weeks, the recurrence rate at 24 weeks was only 4.5% in the dermaPACE group compared with 20% in the Sham-control group.

Secondary Efficacy Endpoints

A secondary efficacy endpoint was calculated based on subjects achieving $\geq 90\%$ wound reduction in area at 12 weeks using the 206-patient ITT population. In the dermaPACE group that met this endpoint, the average median reduction was $>99\%$. From a physician's perspective, a diabetic foot ulcer that achieves $\geq 90\%$ reduction in area is clinically significant and is treated as a clinical success with minimal additional intervention, if necessary. There were 51 out of 107 (48%) dermaPACE subjects that achieved this secondary efficacy endpoint compared with only 31 out of 99 (31%) Sham-control subjects. The rate of complete wound closure or $\geq 90\%$ wound reduction in area at the 12-week time point between dermaPACE and Sham-control was strongly significant ($p=0.016$).

Another secondary efficacy endpoint in this study was the change in wound area from baseline at 12 weeks following initial application of dermaPACE compared with patients receiving Sham-control. By 12 weeks, the average percent reduction in the size of the target ulcer in dermaPACE subjects was 54%, compared with only 7% in the subjects randomized to Sham-control. Within 6 weeks following the initial treatment with dermaPACE, and consistently throughout the 12-week evaluation period, dermaPACE reduced the size of the target ulcer from baseline with high statistical significance compared with subjects randomized to receive Sham-control ($p<0.01$) and remained significant up through and including the final visit at 24 weeks ($p<0.05$).

dermaPACE was also shown to significantly reduce increases in wound area and volume from the outset. Specifically, when comparing initial wound area and response to treatment, a significantly greater proportion of subjects in the Sham-control group experienced enlargement of the target ulcer (28%) compared with subjects treated with dermaPACE (14%), as evidenced by an increase in the size of the target ulcer during the first week following initial application ($p=0.019$).

Robert Galiano, M.D., 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% or better healed. The fact that dermaPACE achieved statistical significance in complete wound closure at 20 weeks is also clinically relevant. This means that after one treatment cycle with dermaPACE, I can potentially delay, or perhaps even eliminate, more costly and invasive wound closure procedures or products and instead rely on a regimen of standard wound care treatments, which has value to me, my staff, and, most of all, my patients."

Mr. Cashman concluded, "The pure study design we implemented provided highly credible, unbiased evidence that dermaPACE alone significantly and positively impacts the wound healing process. Multiple prior studies conducted at respected institutions around the world have shown that the scientific mechanisms activated by dermaPACE technology impact wound healing by increasing blood perfusion and stimulating the body's own angiogenic and positive inflammatory wound healing responses. These pivotal Phase III study results provide new, highly compelling clinical evidence that such a biologic mechanism, when combined with proper wound care, can safely promote the closure of diabetic foot ulcers. 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 as 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.

Conference Call

SANUWAVE management will host an investment community conference call beginning at 11:00 a.m. Eastern time today to discuss the Phase III data, the recent PMA filing and to answer investor questions. Dr. Galiano and Lawrence S. Bass, M.D., the safety monitor for the dermaPACE clinical trial and Clinical Assistant Professor of Plastic Surgery, Department of Plastic Surgery, NYU School of Medicine, will join management on the conference call to discuss the clinical trial's outcomes and design, and answer questions.

Shareholders and other interested parties can participate in the conference call by dialing 877-403-3959 (U.S. and Canada) or 706-902-0367 (international) and entering Conference ID 79173276. A slide presentation will accompany the conference call and will be available on the "Investor Events" section of the Company's website.

A replay of the conference call will be available beginning two hours after its completion through July 19, 2011 by dialing 800-642-1687 (U.S. and Canada) or 706-645-9291 (international) and entering Conference ID 79173276. The audio and the slide presentation will be archived for six months at <http://www.sanuwave.com/investors/investorevents.html>.

Medical Need

Diabetes is common, disabling and deadly. In the U.S., diabetes has reached epidemic proportions. According to the American Diabetes Association, about 27 million people (9% of the total U.S. population) have diabetes, and nearly 2 million new cases are diagnosed in people age 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 to 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. 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.

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.

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 procedures trigger 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 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 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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