



Healing today. Curing tomorrow.

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FOR IMMEDIATE RELEASE

SANUWAVE HEALTH SUBMITS FINAL MODULE OF PMA APPLICATION FOR FDA APPROVAL OF DERMAPACE TO TREAT DIABETIC FOOT ULCERS

Company to Announce 24-Week Pivotal Phase III Clinical Trial Results and Hold Conference Call with Principal Investigators July 12

ALPHARETTA, GA, July 6, 2011 – SANUWAVE Health, Inc. (OTCBB: SNWV) (www.sanuwave.com), an emerging medical technology company focused on the development and commercialization of noninvasive, biological response activating devices in regenerative medicine, today announced that it has submitted to the U.S. Food and Drug Administration (FDA) the third and final module of its Premarket Approval (PMA) application for the dermaPACE[®] device for the treatment of diabetic foot ulcers (DFU).

The 206-patient, randomized, double-blind, 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.

Through the acceptance of a shell agreement in August 2010, SANUWAVE received FDA permission to file the PMA for dermaPACE in a series of three sections or “modules”. In December 2010, the Company submitted the first module, which included preclinical data and the results of prior clinical testing. The Company submitted the second module containing the Quality System and Manufacturing review in January 2011. This final module contained the PMA application, data from the Company’s pivotal Phase III, Investigational Device Exemption (IDE) clinical trial, proposed product labeling, and a summary of safety and effectiveness.

Commenting on today’s announcement, Christopher M. Cashman, SANUWAVE’s President and Chief Executive Officer, said, “We are confident that the compelling clinical outcomes demonstrated in this rigorous double-blinded, sham controlled clinical trial provide credible, unbiased evidence that dermaPACE combined with current standard of care significantly and positively impacts wound healing in these clinically challenging diabetic foot ulcers compared with standard of care alone.”

“We are pleased to submit this strong package of clinical evidence to the FDA in support of our dermaPACE device to treat diabetic foot ulcers. We look forward to a positive response from the Agency so we can bring this novel, promising treatment to the millions of patients who suffer from these debilitating, recalcitrant wounds,” concluded Mr. Cashman.

Conference Call

SANUWAVE will report the top-line 24-week data from its pivotal Phase III clinical trial before the opening of the U.S. stock markets on July 12, 2011, and management will host an investment community conference call beginning at 11:00 a.m. Eastern time that same day to discuss the Phase III data, the PMA filing and to answer investor questions.

Robert Galiano, M.D., a principal investigator in the study and Assistant Professor, Division of Plastic Surgery, Department of Surgery at the Northwestern University Feinberg School of Medicine, and Lawrence S. Bass, M.D., the safety monitor for the dermaPACE clinical trial and a plastic surgeon in private practice in New York City, as well as Professor, Division of Plastic Surgery at the New York University 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 posted at 7:00 a.m. Eastern time on July 12, 2011 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, 10-15 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.

Phase III Study Design

The dermaPACE pivotal Phase III clinical trial was a prospective, randomized, double-blinded, sham controlled, multicenter, 24-week, parallel group study. The goal of the trial was to establish superiority in diabetic foot ulcer healing rates using the dermaPACE treatment compared with sham control, when both were combined with the current standard of care. The standard of care included wet-to-dry dressings and, for some patients, offloading with a walking boot. Secondary trial endpoints included 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 was defined as full skin reepithelialization 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 represented 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 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 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.