



Healing today. Curing tomorrow.

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FOR IMMEDIATE RELEASE

**SANUWAVE UPDATES ON FDA REVIEW OF DERMAPACE
PREMARKET APPROVAL APPLICATION**

ALPHARETTA, GA, December 21, 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 reported it has received a major deficiency letter from the United States Food and Drug Administration (FDA) regarding the FDA's review of the dermaPACE® Premarket Approval Application (PMA) for the treatment of diabetic foot ulcers.

The FDA issues a major deficiency letter to the applicant when the PMA lacks significant information necessary for FDA to complete its review or to determine whether there is reasonable assurance that the device is safe and effective for its intended use. The FDA comments on the application in detail and requests the applicant to amend the application to respond to the cited deficiencies and provide the necessary information.

As previously reported, the primary efficacy endpoint prospectively defined in the dermaPACE pivotal study protocol was the incidence of complete wound closure at 12 weeks following initial application of dermaPACE (active or sham) in ulcers four weeks or older in duration. In the study, dermaPACE increased the proportion of diabetic foot ulcers that closed within 12 weeks by 36% over Sham-control, but this difference was not statistically significant ($p=0.363$). 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, and after discussions with the FDA at the pre-PMA meeting, SANUWAVE conducted a series of secondary analyses of complete wound closure at 12 weeks and at each subsequent study visit out to 24 weeks. The endpoint of complete wound closure reached statistical significance at 20 weeks in the dermaPACE group, and the rate of healing was maintained in the dermaPACE group at 24 weeks. This full 24-week information was filed with the Company's PMA submission to the FDA.

In its recent letter, the FDA cited, among other deficiencies, the dermaPACE study's previously disclosed failure to meet the study's primary endpoint of 100% wound closure compared with Sham-control at the 12-week time point. Among the letter's recommendations to address the above cited deficiency is for SANUWAVE to design and conduct another clinical trial using the findings from any subgroup(s) that may support the safety and effectiveness of the dermaPACE device. The Company is evaluating the comments in the FDA's letter and is considering its formal response, which may include submitting answers to the deficiencies based on further analysis of the existing data. The Company will continue to evaluate how additional clinical data could further support the approvability of the dermaPACE PMA and will discuss with the FDA whether such data will be required and

supportive. The Company anticipates that its evaluation of its response to the letter and its associated interactions with the FDA will take place in the first quarter of 2012.

"We have had an interactive and timely review with the FDA throughout the PMA process and believe our communications have been productive and further the common understanding between SANUWAVE and the FDA regarding our dermaPACE PMA application. We believe our submission provided clinical data which demonstrates that dermaPACE positively impacts wound healing in these clinically challenging diabetic foot ulcers," noted Christopher M. Cashman, President and CEO of SANUWAVE. "We will continue to work toward our goal of a positive approval decision from the FDA so we can bring this novel, promising treatment to the millions of patients who suffer from these debilitating, recalcitrant wounds."

About dermaPACE

dermaPACE, the Company's Pulsed Acoustic Cellular Expression (PACE®) technology for use in acute and chronic wound healing, delivers high-energy acoustic pressure waves in the shock wave spectrum to produce compressive and tensile stresses on cells and tissue structures which is designed to promote angiogenic and positive inflammatory responses, and quickly initiate the healing cascade. This is thought to result in microcirculatory improvement, including increased perfusion and blood vessel widening (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 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. dermaPACE is an Investigational Device in the United States and is limited by Federal law to investigational use only.

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 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.
