



**SANUWAVE Health, Inc.**

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**FOR IMMEDIATE RELEASE**

**SANUWAVE HEALTH SUBMITS TO FDA FIRST MODULE OF PMA APPLICATION FOR  
DERMAPACE FOR THE TREATMENT OF DIABETIC FOOT ULCERS**

*Top-Line Results Expected by Year End and Complete PMA Filing in First Quarter 2011*

**ALPHARETTA, GA, December 10, 2010** – SANUWAVE Health, Inc. (OTC BB: SNWV), an emerging medical technology company focused on regenerative medicine, today reported its submission to the U.S. Food and Drug Administration (FDA) of the first module of the Premarket Approval (PMA) application for the Company's dermaPACE™ device for the treatment of diabetic foot ulcers (DFU).

SANUWAVE received FDA permission through the acceptance of its shell application in August 2010 to file the PMA for dermaPACE™ in a series of three sections or "modules". This first module included preclinical data and results of prior clinical testing. The Company plans to submit the second module containing a quality manufacturing system review prior to year end. The Company expects to file the third module containing data from the recently completed pivotal Phase III clinical trial of dermaPACE™ to treat diabetic foot ulcers, proposed product labeling and a summary of safety and effectiveness in the first quarter of 2011.

Christopher M. Cashman, President and CEO of SANUWAVE, said, "The filing of this first PMA module brings us one step closer to our goal of offering a safe, effective and economical option for the millions of people with diabetes who suffer with chronic foot ulcers. A Class III PMA approval is the most stringent approval level granted in the U.S. for a medical device, and our efforts to obtain this approval for dermaPACE™ are the result of our commitment to a highly credible, disciplined clinical process and to a world-class quality system throughout the Company. We look forward to announcing the top-line results from our Phase III clinical trial and to filing the remaining two modules in support of an FDA approval for dermaPACE™ to treat diabetic foot ulcers."

**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 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 has completed patient follow-up in 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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