



Healing today. Curing tomorrow.

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**FOR IMMEDIATE RELEASE**

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

*Complete PMA Filing Expected Later This Quarter*

**ALPHARETTA, GA, (January 6, 2011)** – SANUWAVE Health, Inc. (OTC BB: SNWV) ([www.sanuwave.com](http://www.sanuwave.com)), an emerging medical technology company focused on the development and commercialization of non-invasive, biological response activating devices in regenerative medicine, announces it has submitted to the U.S. Food and Drug Administration (FDA) the second module of its Premarket Approval (PMA) application for the dermaPACE™ device for the treatment of diabetic foot ulcers (DFU).

Through the acceptance of a shell application 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. This second module contains the Quality System and Manufacturing review. The Company plans to submit the third and final module of the PMA in the first quarter of 2011. This final module will contain the PMA application, data from the Company’s recently completed pivotal Phase III, Investigational Device Exemption (IDE) clinical trial, proposed product labeling, and a summary of safety and effectiveness.

Christopher M. Cashman, President and CEO of SANUWAVE, said, “SANUWAVE has considerable experience with the PMA submission process as we have successfully used this regulatory pathway twice for our Class III Ossatron® device. In addition, we have specific expertise with manufacturing protocols as evidenced by our ISO13485 certification. These diligent efforts underscore our capabilities and our commitment to stringent, company-wide quality systems. The filing of this second PMA module brings us one step closer to our goal of securing approval of dermaPACE™ for the treatment of diabetic foot ulcers.”

**About PACE™**

Pulsed Acoustic Cellular Expression, or PACE™, 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](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 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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