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FOR IMMEDIATE RELEASE

SANUWAVE COMPLETES PATIENT FOLLOW-UP IN PHASE III TRIAL OF DERMACE FOR THE TREATMENT OF DIABETIC FOOT ULCERS

FDA Accepts Company's Modular Premarket Approval Shell Application

ALPHARETTA, GA, September 21, 2010 – SANUWAVE Health, Inc. (OTC BB: SNWV) (www.sanuwave.com), an emerging medical technology company focused on the development and commercialization of non-invasive, biological response activating devices in regenerative medicine, today announced the completion of patient follow-up in the Company's pivotal Phase III, Investigational Device Exemption (IDE) clinical trial with dermaPACE™ for the treatment of diabetic foot ulcers.

A total of 206 patients were enrolled in the trial, which was conducted at 22 sites in the U.S. and two sites in Western Europe. Data entry will be completed in the coming weeks, followed by a final data review and then locking of the database in the fourth quarter of 2010. After the database is locked, the Company will unblind the data, conduct statistical analyses, announce top-line results publicly and draft the clinical study report. This work will culminate in submission of the final Premarket Approval (PMA) module to the U.S. Food and Drug Administration (FDA) late in 2010 or early in 2011.

The dermaPACE™ is the Company's lead product candidate for the global wound care market. It incorporates the Company's PACE™ (Pulsed Acoustic Cellular Expression) technology platform, which delivers a proprietary form of extracorporeal shock wave therapy (ESWT) to treat a wide variety of chronic and acute soft tissue conditions. The U.S. diabetic foot ulcer market is estimated at approximately \$2 billion annually.

Christopher M. Cashman, President and CEO of SANUWAVE, said, "Despite advances in diabetes management, diabetic foot ulcers continue to be the most common cause of hospitalization among diabetics, and diabetes remains the single largest contributing factor to limb loss. Estimates indicate people with diabetes have a 25% lifetime risk for developing a foot ulcer, with half of these ulcers becoming infected. Of these infected ulcers, 1 in 4 will lead to amputation. Early detection and appropriate treatment of diabetic foot ulcers may eliminate the vast majority of amputations. The dermaPACE™, with its novel biologic regenerative effects, holds promise to heal diabetic foot ulcers and increase limb preservation, thus improving quality of life for these patients and their families and significantly easing the economic burden on an overwhelmed healthcare system that cares for these patients."

Mr. Cashman continued, "194 million people globally have diabetes, including 27 million people in the U.S. In any given year in the U.S. there are 3 million diabetic foot ulcers. Diabetes is recognized as a growing and serious global healthcare problem. In the U.S. alone, 54 million people are pre-diabetic, and the occurrence of diabetes onset is on the rise in many countries. It is imperative that caregivers

have access to new, validated advanced wound healing modalities that can improve outcomes for patients suffering with diabetic foot ulcers. The dermaPACE™, as demonstrated by our complete body of clinical work, promotes wound closure and provides treatment in a cost-effective and clinically efficient manner.”

Modular PMA Process Set to Begin

In August 2010 the FDA accepted SANUWAVE’s shell application for dermaPACE™ proposing a modular PMA submission plan containing three sections or “modules.” A modular submission divides the PMA document into modules filed at different times that together form the complete application. This modular approach allows the FDA to review each module separately as soon as it is received, making it possible for manufacturers to receive timely feedback during the review process, and perhaps shortening the time to a final regulatory determination.

The Company will submit the first two modules containing the preclinical data, prior clinical testing and a quality manufacturing system review to the FDA in October 2010. The Company plans to submit the third and final module containing the PMA application, clinical trial data, proposed product labeling and summary of safety and effectiveness late in 2010 or early in 2011.

Mr. Cashman concluded, “Initiating the dermaPACE™ PMA submission is an important milestone for SANUWAVE, as it brings us one step closer to our goal of introducing dermaPACE™ to stimulate wound healing and closure. Our diligent efforts to achieve a Class III PMA approval for dermaPACE™, the most stringent approval level granted in the U.S., will allow SANUWAVE to establish clinical credibility, differentiate our technology and create a significant barrier to entry for potential competitors. These factors, along with our extensive patent portfolio, provide a high degree of market protection and should enhance shareholder value. We look forward to working with the FDA to facilitate the review of this novel regenerative technology.”

Phase III Study Design

The dermaPACE™ Phase III trial is a prospective, randomized, double-blinded, sham-controlled, multicenter, 26-week, parallel assignment study with a primary endpoint of diabetic foot ulcer closure. The goal of the study is to establish superiority in diabetic foot ulcer healing rates using the dermaPACE™ treatment compared with sham control, when both are combined with the current standard of care. The standard of care includes wet-to-dry dressings and, for some patients, offloading with a walking boot. Secondary trial endpoints include 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 is deemed successful if the skin is re-epithelialized without drainage or dressing requirements. The Company plans to announce top-line data immediately following validation of study results and statistical analysis in the fourth quarter of 2010.

About PACE™

PACE™, defined as Pulsed Acoustic Cellular Expression, delivers high-energy acoustic pressure waves to produce compressive and tensile stresses on cells and tissue structures to promote a positive inflammatory response 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 the inflammatory and 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) 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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