SANUWAVE Technology Shown to Proliferate Adult Stem Cells

ALPHARETTA, Ga.--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 announced the publication of peer-reviewed, preclinical data that demonstrate the ability of the Company’s extracorporeal shock wave technology (ESWT) to substantially stimulate proliferation of periosteal progenitor/adult stem cells within the body and significantly increase the quantity and quality of adult stem cells that can be harvested from the cambium layer (the inner osteogenic layer of the periosteum) for select tissue engineering and regenerative medicine applications.

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The authors demonstrated that ESWT effectively proliferates adult stem cells within the periosteum of femurs and tibias in a rodent model, which the authors suggest could then be more efficiently harvested and transplanted for orthopaedic applications, such as fracture or joint repair and human tissue engineering applications. The publication, titled “Extracorporeal Shock Wave-Induced Proliferation of Periosteal Cells,” appears in a recent edition of the Journal of Orthopaedic Research.


Summary of Key Study Findings

- In the tibia, four days after a single treatment, ESWT resulted in a six-fold increase in the number of adult stem cells within the cambium layer and an eight-fold increase in cambium layer thickness. In the femur, also at four days following treatment, ESWT resulted in a three-fold increase in the number of adult stem cells and nearly a five-fold increase in the thickness of the cambium layer.
- The ESWT energy levels used to stimulate the proliferation of adult stems cell did not damage surrounding tissues.
- The elevated presence of certain proteins at the treatment site suggests that ESWT promotes rapid vascularization of bone.
- ESWT has the potential to be a noninvasive, fast, safe and relatively inexpensive way to stimulate periosteal adult stem cell proliferation within the human body that
may be harvested for select tissue engineering and regenerative medicine applications.

Led by Myron Spector, M.D., a professor and researcher at Harvard-MIT Division of Health Sciences and Technology, the authors concluded, “This study successfully demonstrated the use of ESWT as a non-invasive and rapid way of stimulating the periosteal cambium cells to proliferate. The advantage of the proliferated and thickened periosteal layer is 2-fold. Firstly, the proliferated cells provide more cells for surgical or tissue engineering strategies. Secondly, the thickened layer reduces the technical difficulty in harvesting the periosteal cells for use, which increases the probability of successful cambium layer, and not just fibrous layer, tissue harvest. Our model proposes a relatively inexpensive, non-invasive, and safe way to stimulate periosteal cell proliferation.”

According to the study authors, “ESWT stimulated periosteal cells to differentiate down an osteogenic (bone growth) pathway.” Furthermore, “For the large majority of samples, the (outer) fibrous layer (of the periosteum) was structurally unchanged in the ESWT groups when compared with controls. This provides a suturable layer for surgical use, which may be advantageous over mesenchymal stem cells (MSCs) or other cell sources, as the fibrous sheet can act as a delivery vehicle and can support the (adult stem) cells. Future studies are needed to investigate the suitability of the proliferated cells for bone – and cartilage – tissue engineering and regenerative medicine strategies.”

Christopher M. Cashman, President and CEO of SANUWAVE, said, “This exciting, early stage research underscores the potential of our proprietary ESWT platform, defined as Pulsed Acoustic Cellular Expression (PACE®) technology, as an adult stem cell proliferation and differentiation modality. Practical applications in tissue engineering and regenerative medicine may include, among other uses, fracture healing and autograft harvesting for bone and cartilage regeneration, which are very large markets. PACE treatment has the distinct clinical advantage of being noninvasive, safe and more cost effective than current adult stem cell proliferation, harvesting and differentiation methods. Additionally, the findings of this study build upon an already large body of clinical evidence that demonstrates the proliferative and proangiogenic (new blood vessel growth) effects of PACE technology.”

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.