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Sanuwave On Track To Complete Diabetic Foot Ulcer PMA By June 30

Sanuwave Health says it is on track to wrap up a PMA submission by the end of June for its *dermaPACE* wound care device, which treats chronic diabetic foot ulcers with high energy acoustic pressure waves.

The firm currently is readying the third and final module of its PMA submission - including pivotal trial data on 206 patients - after having already submitted the first two modules. Sanuwave hopes to gain FDA approval by early 2012.

“We have a hurdle ahead of us [and] will continue to work closely with FDA to get approval,” Sanuwave CEO Christopher Cashman told “The Gray Sheet” in an interview.



A technician applies DermaPACE to a patient’s diabetic foot ulcer. (Photo: Sanuwave)

Sanuwave submitted preclinical and early clinical data on the device in December, and manufacturing and quality plans in January, which FDA “is already reviewing,” Cashman reported.

Sanuwave estimates a sizeable market, with at least 3 million patients in the U.S. alone who suffer from diabetic foot ulcers each year.

The technology uses high-energy acoustic pressure waves to stimulate new blood vessel formation, and soft tissue and bone regeneration, to heal the wound. The pressure waves work by both compressing and stretching cells in order to generate an inflammatory response for both musculoskeletal and soft tissue, the company explains in background literature.

The energy used is about 80-times greater than that generated by ultrasound machines, according to the company. Sanuwave also notes that acoustic shockwaves have been used safely, and at much higher energy and pulse levels, for over 20 years for lithotripsy procedures to treat kidney stones.

The DermaPACE system consists of a high-energy generator that sits on a cart and a connecting pressure wave applicator that comes in contact with the patient. Physicians using the device can control how deep or shallow the shockwave is, depending on the extent of the condition or area of treatment.

Patients can feel the pressure waves generated by the device but they are not painful, and participants in company's pivotal trial did not require anesthesia, Cashman noted.

Clinical Trial Recently Concluded

Sanuwave's 206-patient pivotal trial was designed to measure the effectiveness of four 20-minute non-invasive dermaPACE treatment sessions administered over the course of two weeks.

The randomized, sham-controlled study, which was completed in 26 weeks, missed its primary endpoint but did show utility, and the firm is confident that the complete data set will be sufficient to support its PMA submission.

The data showed that 36% more diabetic foot ulcer wounds were closed completely within 12 weeks in patients treated with dermaPACE compared to those treated with a sham control, but the number was not statistically significant.

Sanuwave did achieve statistically superior results, however, in an extra "composite analysis" including wounds deemed 90% healed or better, and patients treated with the device were twice as likely to achieve 90%-100% wound closer within 12 weeks versus the sham control group, according to the findings. (See "dermaPACE Misses Endpoint, Shows Utility" - "The Gray Sheet" Dec. 20, 2010.)

The complete study results are "compelling," Cashman maintained.



Sanuwave hopes to gain FDA approval for dermaPACE by early 2012. (Photo: Sanuwave)

as effective while costing significantly less.

Competing products include Advanced BioHealing's *Dermagraft*, a patch that uses natural cells called fibroblasts to heal diabetic foot ulcers. (See in this issue "Shire Nabs Advanced BioHealing Just Prior To Planned IPO")

Other competing products include Organogenesis' *Apligraf*, a diabetic foot ulcer treatment that uses bi-layered, bio-engineered cells to speed wound healing.

Negative pressure wound therapy devices, such as those offered by Kinetic Concepts Inc., also are used for the indication. However, NPWT therapy can be cumbersome since a patient has to wear the device for weeks or longer, according to Cashman, a former KCI executive.

While Sanuwave's pivotal trial missed its primary endpoint, the study did show utility, and the firm says the data is sufficient to support its PMA submission.

The current standard of care for diabetic foot ulcers is essentially cleaning the wound and changing the dressing, Cashman noted. However, such treatment can be relatively ineffective. "When you get into chronic conditions like these diabetic foot ulcers you sometimes need a lot more than that because the blood flow to your extremities is very compromised" and can stunt the healing process, the exec explained.

If approved by FDA, DermaPACE would compete with other available advanced therapies, though Sanuwave asserts that its solution can be just

The dermaPACE treatment could cut costs in half when compared to some alternative advanced therapies on the market, Cashman suggested. And dermaPACE could cost just a quarter of the price of a standard NPWT therapy regimen, the exec said.

Treatment with dermaPACE, including dressings, doctor visits and nursing time, would cost less than \$4,000 over the course of a 12-week treatment period, Cashman estimated. The result would be "significant savings to the health care system," the exec asserted.

dermaPACE is designed to be much cheaper than existing treatments, including biologic options and negative pressure wound therapy.

Sanuwave plans to charge for dermaPACE on a per-procedure basis rather than selling the systems outright. Wound care centers or individual physicians could keep the systems on hand and purchase a treatment kit from Sanuwave that would include a computerized "procedure card" to enable the system.

The firm anticipates that some clinicians may already be familiar with its technology, aiding adoption, since it is similar to that of a system it phased out in 2008 for treating chronic heel pain, Cashman said.

Potential, future indications could range from fracture healing and osteoarthritis treatment to scar modulation, cardiac and spinal fusion care, the exec said, though the latter two options could require partnership or licensing deals.

Based in Alpharetta, Ga., Sanuwave has 28 employees and is currently gearing up for U.S. marketing by preparing to hire reimbursement, sales and support personnel. The firm, which had \$2.3 million in cash on hand as of March 31, netted \$8.5 million in April via a private placement, according to a May 16 filing with the Securities and Exchange Commission.

Sanuwave was founded in 2005 by way of a divestiture from HealthTronics, which is now owned by Endo Pharmaceuticals. The firm went public in 2009 through a reverse merger with publicly traded shell company Rub Music Enterprises. (See "Sanuwave Goes Public Through 'Reverse Merger' With Shell Company" - *"The Gray Sheet"* Oct. 12, 2009.)

By Mark Hollmer