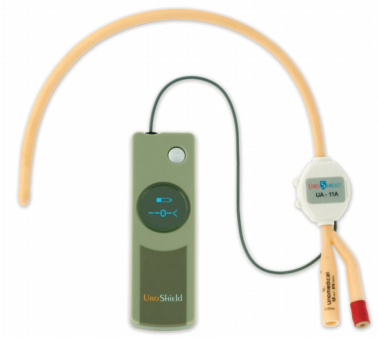
NanoVibronix Announces Successful Interim Trial Results for UroShield™

Demonstrates efficacy preventing catheter-acquired urinary tract infections

Less than 4% using UroShield™ developed infections versus 52% of control group

November 08, 2017 - NanoVibronix, Inc, (NASDAQ: NAOV), a medical device company utilizing the Company's proprietary and patented low intensity surface acoustic wave technology, today announced successful interim trial results for its UroShield™ device. UroShield™ is an ultrasound-based product that is designed to prevent bacterial colonization and biofilm on indwelling urinary catheters and increase antibiotic efficacy, ultimately reducing the incidence of catheter-associated urinary tract infections (CAUTI). UroShield is also intended to decrease pain and discomfort associated with urinary catheter use.



According to the Centers for Disease Control and Prevention, urinary tract infection (UTI) is an infection involving any part of the urinary system, including urethra, bladder, ureters, and kidney. UTIs are the most common type of healthcare-associated infection reported to the National Healthcare Safety Network (NHSN). Among UTIs acquired in the hospital, approximately 75% are associated with a urinary catheter, which is a tube inserted into the bladder through the urethra to drain urine. Between 15-25% of hospitalized patients receive urinary catheters during their hospital stay. The most important risk factor for developing a CAUTI is prolonged use of the urinary catheter.

The trial was conducted at 5 different nursing facilities, in which 51 subjects were evaluated with 26 in the active/treatment group and 25 in the control group. All patients had been treated for at least one incident of a catheter-acquired urinary tract infection (CAUTI) requiring antibiotics in the preceding 6 months prior to trial initiation.

At the 90-day evaluation, 13 of 25 subjects (52%) in the control group developed a CAUTI requiring systemic antibiotics while only 1 of 26 patients (4%) in the UroShield™ group required antibiotics.

All study subjects had an initial colony count of greater than 100,000 CFU cultured from their urinary tract. At thirty days, all subjects within the control group showed no change in the number of their bacteria count which was greater than 100,000 CFU, while those in the treatment group showed a reduction to 10,000 CFU in 15 of 26 subjects and only 1,000 CFU in 10 of 26 subjects.

Brian Murphy, Chief Executive Officer of NanoVibronix Inc., commented, "We are pleased to report the interim results of this latest study, demonstrating a material reduction in the rate of CAUTI. These successful results reinforce our earlier data demonstrating a significant reduction in infection rates and bacterial colonization on catheter devices when using UroShield™. We believe that the fact that UroShield already has European and Canadian marketing clearance, a strong safety profile including our predicate devices, as well as strong data from this and other ongoing studies, should help to accelerate 510(k) marketing clearance with the United States Food and Drug Administration. We also plan to use this evidence to bolster our European and Canadian marketing efforts while working through the FDA application, and plan to start developing a distribution network in the U.S. in advance of marketing clearance."

"The reduction in the rate of CAUTI further illustrates the potential to reduce healthcare costs, improve outcomes, and enhance quality of life for patients. We are very encouraged by the outlook for this product, as we are not aware of any other local device that has demonstrated this type of short-term and long-term prevention of CAUTI in the catheterized patient population."