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NanoVibronix Announces Publication of Study Measuring the Effect of Surface Acoustic Waves on Bacterial Load and Preventing Catheter-Associated Urinary Tract Infections

UroShield™ reduced Colony Forming Units (CFU) count from >100,000 to 10,000 CFU or less in 25 of 29 patients in the treatment group

No reported infections in the treatment group versus 27% symptomatic treated infections in the control group

Effects of UroShield lasted beyond the time of active treatment

ELMSFORD, N.Y., Dec. 06, 2018 (GLOBE NEWSWIRE) -- **NanoVibronix, Inc, (NASDAQ: NAOV),** a medical device company utilizing the Company's proprietary and patented low intensity surface acoustic wave (SAW) technology, today announced the publication of an independent study, entitled “The Effect of Surface Acoustic Waves on Bacterial Load and Preventing Catheter-Associated Urinary Tract Infections (CAUTI) in Long Term Indwelling Catheters,” which was published in the December 2018 issue of Medical & Surgical Urology, a leading peer-reviewed journal in the field of urology. The study publication is available at: https://www.omicsonline.org/open-access/the-effect-of-surface-acoustic-waves-on-bacterial-load-and-preventing-catheter-associated-urinary-tract-infections-cauti-in-long-t-2168-9857-1000210.pdf

UroShield™ is a patented ultrasound-based product that is designed to prevent bacterial colonization and biofilm on indwelling urinary catheters, increase antibiotic efficacy, ultimately reducing catheter associated urinary tract infection (CAUTI). UroShield is also intended to decrease pain and discomfort associated with urinary catheter use.

According to the Centers for Disease Control and Prevention (CDC), urinary tract infections are the most common type of health care-associated infection, accounting for more than 30 percent of reported health care-associated infections. Among UTIs acquired in hospital settings, 70 to 80 percent are associated with an indwelling urinary catheter. CAUTI has been associated with increased morbidity, mortality, hospital cost and length of stay.

This study was a double blinded randomized control trial of the UroShield™ device. 55 patients in a skilled nursing facility chain treated with long term indwelling catheters were evaluated. There was a significant difference between the treated group and the placebo

group in the number of Colony Forming Units (CFU) present upon evaluation, as well as on the number of treated UTI's. The effect lasted beyond the time of active treatment.

At baseline, the CFUs for all groups both in the catheter and urine assessment were 100K or greater. There was thus no variability between or within groups. The sham control group's CFU counts in both the catheter and urine assessment, remained at 100K for each subsequent assessment (30, 60, and 90 days). Compared to baseline, the treatment group showed significant improvement at 30 days. There was a statistically and clinically significant reduction in the number of CFUs in the treatment group as compared to the control group.

Mean improvement advantage in treatment vs control was 87.2K CFU, (t (53) 18.1, $p<0.001$) at thirty days. At 60 days the mean improvement advantage in treatment vs control was 87.5K CFU, (t (53) 18.1, $p<0.001$). At 90 days the mean improvement advantage in treatment vs control was 79.3K CFU, (t (53) 12.4, $p<0.001$).

After cessation of treatment in the active group at 30 days, there was a minimal increase in CFU count at both 60 and 90 days. In the same group, there was no statistical difference in the decrease of CFU count from 30 to 60 days after treatment, t (28)=1. p= .326, however there was a marginally significant increase in CFU from 60 to 90 days for the active group (28)=1.7 p= 0.09.

At baseline, every enrolled patient had been treated for infection during the 90 days prior to enrollment. Compared to baseline, the treatment group showed significant statistical and clinical improvement (100%) at 30 days relative to the sham control (73%). There were no reported infections in the treatment group while in the control group there were seven reported infections.

At 90 days after treatment, the treatment group showed a significantly stronger improvement (89.7%) compared to the sham control (46.2%). There were three reported infection in the treatment group, while in the control group there were fourteen reported infections requiring antimicrobial therapy. (logistic regression B=2.3, Wald Chi-Square (df=1) =10.1, p=0.001.)

At 30 days post-treatment there were no treated infections for both the urinary and suprapubic catheters in the treatment group. At 90 days after treatment, the urinary catheter had fewer treated infections (4.3%) compared to the suprapubic catheter (33.3%). This difference was marginally significant B=2.4, Wald Chi-Square= (df=1) =3.2, p=0.074.

The study concluded: "The UroShield™ device was shown to be effective in significantly reducing the number of CFUs in patients with indwelling catheters. It was also shown to be effective in reducing the number of treated UTIs in this patient population. SAW in the form of the UroShield™ device is an effective tool in the prevention of CAUTI and while further evaluation is encouraged, can be safely utilized with a high likelihood of success."

Brian Murphy, Chief Executive Officer of NanoVibronix, commented, "This publication is a major independent validation of the UroShield device. The study clearly demonstrated the ability of UroShield to dramatically reduce CFUs and there were no reported infections in

the treatment group. Importantly, CAUTI is a leading cause of morbidity and mortality within hospitals and skilled nursing facilities, as well as major financial burden to the healthcare system. We believe UroShield™ has the potential to both save lives and dramatically reduce healthcare costs. This study demonstrates a clinical effectiveness we have not seen by any other intervention known to us. I am encouraged and delighted with the results, which should serve us well as we seek additional regulatory approvals for UroShield."

About NanoVibronix

NanoVibronix Inc. (NASDAQ: NAOV) is a medical device company headquartered in Elmsford, New York with research and development in Nesher, Israel, that is focused on developing medical devices utilizing its proprietary and patented low intensity surface acoustic wave technology. The company's technology allows for the creation of low-frequency ultrasound waves that can be utilized for a variety of medical applications, including the disruption of biofilms and bacteria colonization, as well as providing pain relief. The devices can be administered at home, without the assistance of medical professionals. The company's primary products include PainShield, UroShield and WoundShield. Additional information about the company is available at: www.nanovibronix.com.

Forward-looking Statements

This press release contains "forward-looking statements." Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company's control, and cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with (i) market acceptance of our existing and new products, (ii) negative clinical trial results or lengthy product delays in key markets, (iii) an inability to secure regulatory approvals for the sale of our products, (iv) intense competition in the medical device industry from much larger, multinational companies, (v) product liability claims, (vi) product malfunctions, (vii) our limited manufacturing capabilities and reliance on subcontractors for assistance, (viii) insufficient or inadequate reimbursement by governmental and other third party payers for our products, (ix) our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful, (x) legislative or regulatory reform of the healthcare system in both the U.S. and foreign jurisdictions, (xi) our reliance on single suppliers for certain product components, (xii) the fact that we will need to raise additional capital to meet our business requirements in the future and that such capital raising may be costly, dilutive or difficult to obtain and (xiii) the fact that we conduct business in multiple foreign jurisdictions, exposing us to foreign currency exchange rate fluctuations, logistical and communications challenges, burdens and costs of compliance with foreign laws and political and economic instability in each jurisdiction. More detailed information about the Company and the risk factors that may affect the realization of forward looking statements is set forth in the

Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's web site at http://www.sec.gov. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

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