First Patient Enrolled In CEASE VAP Study of CeraShield ETT

PARK CITY , UTAH , UNITED STATES , February 24, 2023 /EINPresswire.com/ -- N8 Medical today announced that Kingston General Hospital (Kingston, Ontario) enrolled the first patient in its CEASE VAP study.

CEASE VAP is a Canada-funded randomized, controlled, single-center study of up to 800 patients to determine the ability of N8 Medical's CeraShield Endotracheal Tube (ETT) to reduce Ventilator Associated Pneumonia (VAP).

VAP is the leading hospital acquired infection among mechanically ventilated ICU patients and is a significant cause of morbidity, mortality, and added expense; half of all antibiotic use in the ICU is for VAP. Research has linked the growth of bacterial biofilms on the surfaces of the endotracheal tube as a cause of VAP. Biofilms are slime-like aggregations of millions of bacteria and fungi that rapidly grow on medical devices within hours once these have been removed from their sterile packaging and placed in contact with the patient.

"This study will test the hypothesis that preventing biofilm growth on ETTs can reduce the incidence of VAP, shorten stays in the ICU, and improve patient health. Our prior first-in-human study showed that the CeraShield ETT was able to prevent bacterial colonization in 51 out of 52 endotracheal tube aspirate samples with not a single case of a Gram-negative pathogen colonization. We viewed those results as promising and that led us to design and obtain peer reviewed funding for this large study," said Professor John Muscedere, the study's principal investigator. "If the study is successful, I believe that the CeraShield ETT will be widely adopted as part of routine care in the ICU," he added. Dr. John Muscedere, MD, FRCPC, is an intensivist at Kingston Health Sciences Center (KHSC), and Professor of Critical Care Medicine in the Faculty of Health Sciences at Queen's University. He also serves as the Research Director of the Critical Care Program at Queen's and KGH.

The study will compare the CeraShield ETT's efficacy to that of an uncoated endotracheal tube with subglottic suctioning function. The CeraShield ETT is an endotracheal tube coated by a ceragenin compound designed to prevent biofilm fouling of the device. Ceragenins are members of a class of compounds invented by Dr. Paul B. Savage Professor of Chemistry and Biochemistry at BYU (Provo, Utah) that mimic the activity of naturally occurring antimicrobial peptides which

form a key component of the human body's innate immune system. The CeraShield coating is able to prevent bacteria and fungi from attaching to the surfaces of medical devices while killing pathogens on contact as well.

There are now over 100 peer reviewed journal articles on ceragenins. The CeraShield™ technology is a platform technology applicable to nearly all indwelling medical devices. The CDC estimates that 65% of all hospital acquired infections (HAIs) are caused by biofilm fouling of indwelling medical devices. The NIH has estimated that HAIs add more than $30 billion in cost to the US healthcare expenditures each year. For a sample of freely available research, see www.n8medical.com/publication. Carl Genberg, N8 Medical's co-founder and Chief Scientific Officer said, "We look forward to the study's completion and sharing the results with policy makers and the healthcare community. We fully agree with former FDA commissioner Dr. Scott Gottlieb's view that the best approach in addressing the antimicrobial resistance crisis is to prevent patients from becoming infected in the first place."

The CeraShield ETT is approved for clinical use in Canada. FDA has designated the CeraShield ETT as a "breakthrough device." The ETT is investigational in the US but approved in multiple countries outside of the US.

About VAP
Ventilator associated pneumonia (VAP) is a hospital acquired infection that causes morbidity and increased health care costs in mechanically ventilated critically ill patients. VAP increases the duration of mechanical ventilation by approximately 7 days, duration of ICU stay by 8 days, hospitalization by 11 days and is estimated to cost $10,000 - $15000 USD per occurrence. VAP has an attributable mortality that is estimated to be between 6 and 13% and which increases if therapy is inadequate or delayed, or if it occurs in high-risk populations. In spite of efforts to eradicate it, VAP continues to occur significantly with an incidence of approximately 10-20 cases/1000 ventilator days and in some countries has been found to afflict approximately 50% of mechanically ventilated COVID-19 patients. The pathogens causing VAP are increasingly resistant to antibiotics. Consequently, VAP has become much more difficult to treat and will become increasingly so in the future.

About N8 Medical, LLC
N8 Medical, LLC (N8 Medical) is a clinical-stage medical device company focused on commercializing medical devices that incorporate a novel class of active compounds called ceragenins. N8 Medical licenses the use of the Ceragenin technology from Brigham Young University (BYU, Provo, Utah).

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