N8 Medical Obtains Brazilian Regulatory Approval for its CeraShield Infection Prevention ® Endotracheal Tube

Medical Device is Designed To Prevent Potentially Lethal Complications and Reduce Cost of Care in Patients who Require Mechanical Ventilation in ICUs.

DUBLIN, OHIO, USA, November 15, 2021 /EINPresswire.com/ -- N8 Medical Obtains Brazilian Regulatory Approval for its CeraShield Infection Prevention ® Endotracheal Tube

Medical Device is Designed To Prevent Potentially Lethal Complications and Reduce Cost of Care in Patients who Require Mechanical Ventilation in Intensive Care Units (ICUs). Could save hundred of millions (USD) annually in Brazil alone.

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>
> *Robert D. Mitchell*

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N8 Medical ("N8") today announced that its subsidiary N8 Medical LLC as received regulatory approval from Agência Nacional de Vigilância Sanitária (ANVISA) to market its Infection Prevention Endotracheal Tube in Brazil. This approval follows Health Canada's recent approval in Canada. It is estimated that over 500,000 endotracheal tubes are used annually in Brazil for patients who require mechanical ventilation for over 48 hours. Approximately 125,000 of those patients will develop Ventilator Associated Pneumonia (VAP) with an added cost of between $7,000 to $21,000 USD for each such case. The total cost of care for VAP patients in Brazil exceeds $800 million USD annually. Worldwide, the costs exceed $10 billion annually.

VAP is linked to the rapid bacterial and fungal fouling of endotracheal tubes after the tubes are inserted into the patient's airway and connected to a mechanical ventilator. These pathogens form antibiotic resistant biofilms on the tube's surfaces that secrete endotoxins and help trigger inflammatory cytokine cascades. Bioflms are a slime like aggregation of millions of bacterial or fungal colony forming units (CFUs). The biofilms act as a reservoir of potentially lethal infectious agents and dislodge from the tube over time into the patient's lower respiratory tract leading to pneumonia. In vitro testing of CeraShield Infection Prevention Endotracheal Tube has shown that the tube is able to reduce pathogen colonization by over 6 logs compared to uncoated

controls. The tube is active against all ESKAPE pathogens, Candida auris and COVID-19.

"In my view, the CeraShield Infection Prevention Endotracheal Tube offers a novel solution to the growing healthcare crisis of VAP and multidrug resistant bacterial, fungal and viral infections." said Mr. Robert D. Mitchell, N8 Medical's new CEO. "I look forward to the positive impact N8 products will have to significantly improve patient outcomes and reduce healthcare costs around the world."

ABOUT N8 MEDICAL
N8 is a clinical-stage company focused on developing innovative anti-infective and anti-inflammatory medical devices and pharmaceutical solutions based on synthetic mimics (Ceragenins) of the human innate immune system. The CeraShield Infection Prevention technology is a platform technology applicable to nearly all medical devices that are in contact with the patient for more than 24 hours .There are now over 100 peer reviewed journal articles on the technology and 32 issued US patents.

N8 Medical (www.N8Medical.com), headquartered in Dublin, Ohio, is a privately-held biotechnology company developing a platform of pharmaceuticals and medical devices based on the platform Ceragenin technology invented by Professor Paul B Savage and in-licensed from BYU (Provo, UT). The statements in this release have not been evaluated by ANVISA, Health Canada or the U.S. Food and Drug Administration.

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