FDA grants QIDP Designation For Kinnear's CSA-131 drug for Life-threatening Pseudomonas Bacterial Infections in CF

FDA QiDP designation is a signifcant milestone


Pseudomonas Lung Infection

PARK CITY, UTAH, UNITED STATES, July 31, 2023 /EINPresswire.com/ -- Kinnear Pharmaceuticals, LLC, a subsidiary of N8 Medical, Inc. today announced the U.S. Food and Drug Administration (FDA) has granted Qualified Infectious Disease Product (QIDP) Designation for CSA-131 for the prevention and treatment of life threatening Pseudomonas infections in patients with Cystic Fibrosis. CSA-131 is a synthetic non-peptide mimic of the endogenous antimicrobial peptide LL-37 which forms a key component of the body's innate immune system which is essential to preventing and treating lung infections. Many patients with Cystic Fibrosis have recurrent lung infections from the potentially lethal Gram negative Pseudomonas aeruginosa bacterial pathogen as the activity of LL-37 is impaired by high salt concentration and sticky CF sputum that is characteristic of Cystic Fibrosis. This is based on the genetic impairment of the chloride ion channel in the mucous membranes of CF patients. Unlike LL-37, CSA-131's antimicrobial activity is not deactivated by high salt concentrations or sticky mucous. The genetic defect in innate immunity in CF patients has been partially overcome by the development, FDA approval of introduction of Vertex Pharmaceuticals (NYSE:VRTX) revolutionary CFTR modulatory drugs. However, recurrent Pseudomonas bacterial lung infections still remain an important problem in this patient population and the Cystic Fibrosis Therapeutics Foundation has helped fund the development of CSA-131 to help meet this unmet medical need. The leading cause of early death in CF patients is recurrent Pseudomonas infections which destroy the elasticity of lung tissue making it impossible to breath. CF patients have an average life expectancy of 40 years.

> Pseudomonas aeruginosa is a common potentially lethal pathogen for patients with cystic fibrosis as well as ventilator associated pneumonia. The development of CSA-131 is a welcome advance"
> *Professor Michael Niederman*

"Pseudomonas aeruginosa is a common pathogen for patients with cystic fibrosis and ventilator

associated pneumonia. It leads to high rates of morbidity and mortality due to its complex mechanisms of injury and relative resistance to antibiotic therapy. Prevention is key, but we need new approaches and the development of CSA-131 is a welcome advance" said Professor Michael Niederman, Chairman of N8 Medical's Scientific Advisory Board. "Published research has shown that CSA-131 is highly effective against strains of Pseudomonas that are resistant to Tobramycin and Colistin, two commonly used anti-infective drugs" said Carl Genberg, CEO of Kinnear Pharmaceuticals. "The QIDP Designation shows the importance of CSA-131 for treating serious or life-threatening infections. The QIDP designation grants five years of additional market exclusivity and the potential for fast-track designation. allows us to work even closer with the FDA to bring patients a new treatment faster."

The QIDP designation is part of the GAIN Act which was enacted to spur antibiotic drug development. It provides certain incentives for the development of new antibiotics, including priority review and eligibility for the FDA's Fast Track Designation, and a five-year regulatory exclusivity extension.

About CSA-131 and medical device applications.
CSA-131 is a member of the class of Ceragenin compounds invented by Professor Paul B. Savage, the Reed M. Izatt Professor of Chemistry and Biochemistry at Brigham Young University (BYU, Provo, Utah). CSAs are a platform technology with wide application. Since 2019, Ceragenins have been the subject of overt 100 peer reviewed journal articles of which 50 relate to Cystic Fibrosis. Research has shown that CSA-131 is active against all ESKAPE pathogens as well as COVID-19 and the fungal pathogens Candida auris and Aspergillus. A publicly available selection of peer reviewed journal articles is available at www.n8medical.com/publications.

About our Medical Device Platform to Prevent HAIs.

Aside from the use of CSA-131 as an inhaled drug for CF patients, N8 Medical has also developed a CSA-131 coated endotracheal tube designed to prevent Ventilator Associated Pneumonia (VAP) in mechanically ventilated ICU patients. FDA has designated the CeraShield Endotracheal Tube as a "breakthrough device" pursuant to the 21st Century Cures Act. That device is now approved for routine clinical use in Canada, Brazil and Colombia and other ex-US countries. A large clinical study -- the CEASE-VAP study – is currently underway at Kingston General Hospital in Kingston, Ontario led by Professor John Muscedere to evaluate the comparative efficacy of the CeraShield ETT vs. an uncoated ETT with subglottic suctioning feature in preventing VAP. Over 125 patients have been enrolled with a target enrollment of 400 patients. Biofilm fouling of endotracheal tubes has been identified as the causative agent of VAP. Another clinical study is underway at Prime Hospital in the UAE with additional studies planned in Saudi Arabia, Panama and Colombia. As with CF, Pseudomonas aeruginosa is also a leading lethal pathogen in VAP. CDC estimates that 65% of all hospital acquired infections are caused by biofilm fouling of indwelling medical devices. NIH estimates that hospital acquired infections add over 30 dollars annually to the US healthcare expenditures. One of the notable features of CSA-131 is its ability to prevent and eradicate bacterial and fungal biofilms at clinically relevant concentrations.

N8 Medical has also received 3 SBIR grants (two Phase 1 and one Phase 2) to support the development of CSA-131 coated hemodialysis catheters, pedicle screws and pacemaker envelopes to reduce the incidence of hospital acquired infections. “We believe that our Ceragenin technology has the potential to transform the practice of medicine in multiple verticals and we look forward to the day when this technology is widely adopted to save many lives and avoid the billions of dollars in annual costs of bacterial and fungal infections” said Robert D. Mitchell, CEO of N8 Medical, Inc., Kinnear Pharmaceutical’s parent company.

For more information see www.N8medical.com www.Kinnearpharma.com

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