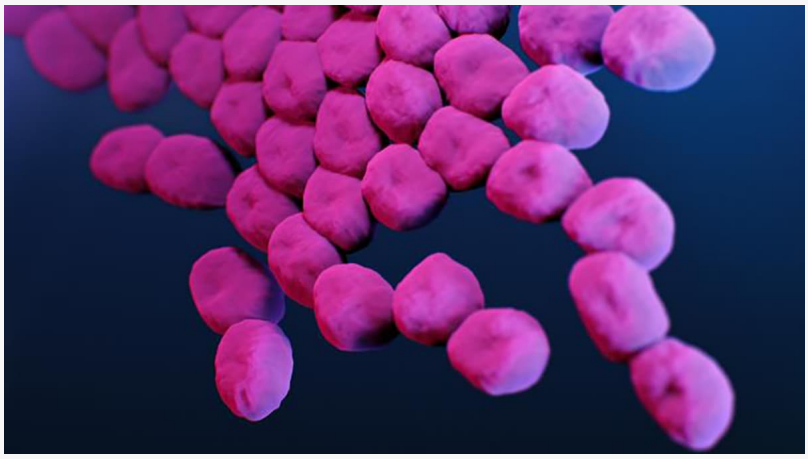
FDA Grants QIDP Designation to Kinnear Pharma for treatment of Acinetobacter baumannii Infections

FDA QiDP designation is the 4th issued to Kinnear establishing Kinnear as a leader in the fight against antimicrobial resistance (AMR).


Acinetobacter

PARK CITY, UTAH, UNITED STATES, July 23, 2024 /EINPresswire.com/ -- Kinnear Pharmaceuticals, LLC and Kinnear Pharma AUS Pty Ltd, subsidiaries of N8 Medical, Inc. today announced U.S. Food and Drug Administration (FDA) Qualified Infectious Disease Product (QIDP) Designation for CSA-131 for the prevention and treatment of life-threatening Acinetobacter baumannii Infections in patients with Cystic Fibrosis. Kinnear previously received QIDP Designations for the prevention and treatment of infections caused by Candida auris, Aspergillus, Pseudomonas, and Klebsiella pneumoniae pathogens in patients with Cystic Fibrosis.

“The QIDP designation highlights CSA-131's significance in treating severe infections and also secures five additional years of market exclusivity and the prospect for expedited FDA processes, facilitating faster patient access to this innovative treatment,” said Carl Genberg, CEO of Kinnear Pharmaceuticals.

CSA-131, developed as an inhaled drug, leverages the unique properties of Ceragenins, a synthetic mimic of LL-37, an essential antimicrobial peptide in the body’s innate immune defense, particularly against lung infections. Ceragenins exhibit broad-spectrum activity against a variety of pathogens, including gram-positive and gram-negative bacteria, fungi, and multidrug-resistant strains such as MRSA, colistin-resistant Acinetobacter, Pseudomonas, and fluconazole-resistant Candida auris. Ceragenins also inhibit lipid-enveloped viruses, including COVID-19.

“Due to its unique capability to efficiently destroy bacterial membranes and prevent biofilm development, Ceragenins show great promise as a potential solution for treating multi-drug-

resistant pathogens like A. baumannii, urgent threats for which doctors and hospitals have few options," said Dr. Robert Bucki, Professor of Medical Microbiology at the Medical University of Białystok.

The World Health Organization has designated Acinetobacter baumannii a critical-priority pathogen, while the US Centers for Disease Control and Prevention labels it an urgent threat, primarily due to its rapid development of resistance to numerous antibiotics, such as carbapenems, complicating treatment efforts. Those at the highest risk for A. baumannii infections include ICU patients requiring mechanical ventilation, patients with extended hospital admissions, and those with weakened immune systems.

About CSA-131

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). Since 2019, Ceragenins have been the subject of over 300 peer-reviewed journal articles of which 50 relate to Cystic Fibrosis.

About Kinnear Pharmaceuticals Kinnear Pharmaceuticals (www.Kinnearpharma.com) is a subsidiary of N8 Medical, Inc. (www.n8medical.com), a holding company dedicated to the broad application of Ceragenins. N8 Medical, Inc. focus includes the commercialization of CeraShield technology, a specialized coating for medical devices aimed at preventing hospital-acquired infections (HAIs).

About N8 Medical, Inc.

N8 Medical, Inc. has a number of Ceragenins-based medical applications including CeraShield, a CSA-131 coated endotracheal tube designed to prevent Ventilator Associated Pneumonia (VAP) in mechanically ventilated ICU patients and received three 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. For more information see www.N8medical.com www.Kinnearpharma.com

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