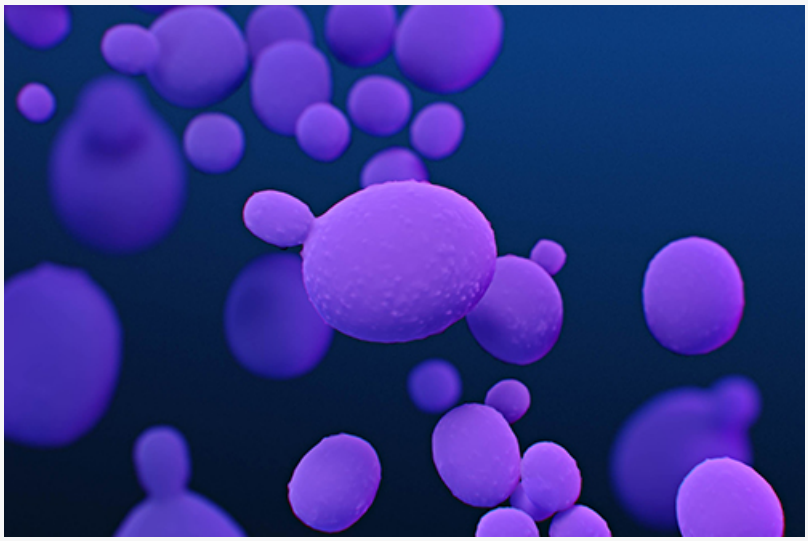
FDA Grants QIDP Designation for Drug to Treat Candida Auris and Aspergillus fungal infections

This is the second QIDP Designation granted to Kinnear Pharmaceuticals


Candida auris

PARK CITY, NV, UNITED STATES, November 15, 2023 / EINPresswire.com/ -- FDA grants QIDP Designation For Kinnear's CSA-131 drug for Life-threatening Candida auris and Aspergillus fungal infections in Cystic Fibrosis patients

FDA QiDP designation is a significant milestone

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 Candida auris and Aspergillus fungal 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. Patients with Cystic Fibrosis have recurrent lung infections and are at high risk for infections from Candida auris and Aspergillus fungal infections.

> Peer reviewed research by the CDC and others have shown that CSA-131 is a promising advance in the battle against serious fungal infections"
>
> *Carl Genberg*

In CF patients, the body's innate immune system key component --- a long chain peptide known as 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 bacterial and fungal lung infections still remain an important problem in this patient population. The Cystic Fibrosis Therapeutics Foundation has helped fund the development of CSA-131 to help meet this unmet medical need.

Candida auris (C. auris) is a type of yeast that can cause severe illness and spreads easily among patients in healthcare facilities. It is often resistant to antifungal treatments, which means that the medications that are designed to kill the fungus and stop infections do not work.

C. auris mostly affects patients with severe underlying medical conditions and requiring complex medical care. Patients with invasive medical devices like breathing tubes, feeding tubes, catheters in a vein, or urinary catheters tend to be at increased risk for getting C. auris and developing an infection. The CDC has designated Candida auris as an serious medical threat.

Approximately 60% of CF patients are infected with Aspergillus fumigatus and its presence has been associated with accelerated lung function decline.

“Published research has shown that CSA-131 is highly effective against strains of Candida auris and Aspergillus -- even those that are pan resistant” said Carl Genberg, CEO of Kinnear Pharmaceuticals, a subsidiary of N8 Medical. “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 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. 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

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