

NeuroSense Therapeutics Receives European Orphan Drug Designation for ALS Drug

NeuroSense, a biotech company developing treatment for ALS, has been granted orphan designation for their first drug, PrimeC, from the European Medicines Agency.

HERZLIYA, Israel, Jan. 12, 2021 /PRNewswire/ -- **NeuroSense Therapeutics**, a clinical-stage biopharmaceutical company, focusing on the discovery and development of targeted innovative therapeutics for neurodegenerative diseases. Their treatment for Amyotrophic Lateral Sclerosis (ALS), based on a novel combination drug therapy aiming at slowing or halting the disease progression, has received orphan designation from the EMA (European Medicines Agency) for their first candidate, PrimeC. This decision from the EMA complements an earlier orphan designation which was granted in 2020 by the American Food and Drug Administration. Together, these designations grant PrimeC seven and ten years of market exclusivity in the US and European Union, respectively

PrimeC, a unique combination drug, has recently shown promising clinical results based on the interim analysis of its phase IIa clinical trial. The results were recently presented at two key ALS conferences, the International MND Conference and the ALS One symposium, where they gained much interest. The trial currently underway at the Sourasky Medical Centre in Tel Aviv, is expected to run until February of 2021.

The decision by the EMA to grant orphan designation to PrimeC comes on the heel of another achievement which saw NeuroSense granted a Seal of Excellence by the European Commission, indicating a vote of confidence in NeuroSense's scientific and clinical programs.

Alon Ben-Noon, CEO of NeuroSense Therapeutics, stated: "We are encouraged by these accomplishments and are looking forward to expediting the development of PrimeC in Europe, the US and globally. Our team at NeuroSense is dedicated to bringing PrimeC to patients suffering from the debilitating disease that is ALS. Together with our Scientific Advisory Board, which was recently strengthened by the addition of world-renowned ALS key opinion leaders, Prof. Merit Cudkowicz, Chief of Neurology at Mass General Hospital, Prof. Orla Hardiman from Beaumont Hospital and Dr. Jinsy Andrews from Columbia University, we expect to present a novel treatment option for ALS patients in the near future."

Dr. Oron Yacoby-Zeevi, NeuroSense's Chief Scientific Officer adds: "It is a great honour for me and all of us at NeuroSense Therapeutics to be working closely with world renowned scientists and clinicians, all of whom have impressive track records of ALS clinical practice and research, and to jointly direct and accelerate the development of PrimeC for the benefit of ALS patients."

About NeuroSense Therapeutics

NeuroSense Therapeutics is a clinical stage drug development company founded in 2016, developing ground-breaking treatment for ALS patients, as well as for patients suffering from other neurodegenerative diseases.

In pre-clinical models of ALS, PrimeC showed outstanding results. These results were significantly superior to the outcome produced by other investigational or approved drugs when tested in these models.

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