

NeuroSense Therapeutics Receives Orphan Drug Designation for Amyotrophic Lateral Sclerosis (ALS) Drug, and Announces Initiation of Two Clinical Studies in ALS

The clinical trials initiated in the United States and in Israel will evaluate safety, tolerability and efficacy of PrimeC, NeuroSense's product for ALS patients.

HERZLIYA, Israel, Feb. 6, 2020 [/PRNewswire/](#) -- **NeuroSense Therapeutics**, a Biotech company developing PrimeC, a combination drug which aims to slow or halt ALS progression, announced today the initiation of two clinical studies to evaluate the benefit of PrimeC for ALS patients. A Phase IIa study is being conducted in Israel at Tel-Aviv Sourasky Medical Center (TASMC), by Prof. Vivian Drory. A similar study is being conducted in the USA at two sites: BNI (The Barrow Neurological Institute) in Phoenix Arizona, by Prof. Jeremy Shefner and Columbia University in NYC, by Dr. Jinsy Andrews. The studies plan to enroll 45 patients, 15 at each site. In addition to safety and tolerability, the company will evaluate the drug's efficacy and ability to slow disease progression and to improve quality of life.

PrimeC targets two fundamental mechanisms underlying the pathogenesis of ALS. The two clinical studies were initiated following exceptional results PrimeC achieved in pre-clinical models of ALS. In these studies, conducted on two different zebrafish models, each with a different ALS-causing mutation, the transgenic fish were treated either with PrimeC or left untreated. The swimming abilities of the PrimeC treated ALS fish increased drastically compared to the controls, and significantly more than with any other compound previously tested in these models. Furthermore, the analysis of motor neurons, neuromuscular junctions and aspects of the immune system in the ALS treated fish, indicated that PrimeC is neuroprotective.

"PrimeC, developed by NeuroSense, was shown to be very successful in pre-clinical studies and we are glad to be testing it in our clinic now, hopeful to see how it will affect the patients," said Prof. Vivian Drory, ALS expert from TASMC. "Patients are excited to participate in the trial and the recruitment rate is very high." Jeremy Shefner, Chair of Neurology at the Barrow Neurological Institute, commented: "PrimeC has intriguing preclinical data and we expect a good safety profile. It is gratifying to be able to offer this novel experimental therapy to patients."

Alon Ben-Noon, CEO of NeuroSense Therapeutics, added: "We are excited by the potential PrimeC holds to benefit ALS patients. We are pleased to be evaluating it in these patients, providing them hope while testing the drug's efficacy. The special connection the company has with patients and their families contributes to the way we progress in our development, and we are thankful for this opportunity. We hope and expect to see positive interim results within several months. True to our mission statement, NeuroSense has taken upon itself to rapidly advance research and development towards a beneficial therapy in the ALS field."

NeuroSense has recently received an orphan drug designation from the FDA for the use of PrimeC to treat ALS. The designation grants PrimeC seven years of market exclusivity in the US.

About ALS

ALS, also known as Lou Gehrig's disease, is a neurodegenerative disease, characterized by the degeneration of motor neurons, leading to progressive paralysis of all voluntarily innervated muscles, therefore affecting mobility, balance, communication, swallowing, and breathing. Death typically occurs 2-4 years after diagnosis, usually due to respiratory failure. There are approximately 30,000 ALS patients in the US, with 6,000 new cases diagnosed every year.

About NeuroSense Therapeutics

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

The rationale behind the novel pathological targets of NeuroSense's drug, PrimeC, is supported by world renowned ALS experts and global Key Opinion Leaders.

In pre-clinical studies, PrimeC showed outstanding results, significantly superior to any other outcome seen in this model before.

For more information, contact: info@neurosense-tx.com

<https://neurosense.investorroom.com/2020-02-06-NeuroSense-Therapeutics-Receives-Orphan-Drug-Designation-for-Amyotrophic-Lateral-Sclerosis-ALS-Drug.-and-Announces-Initiation-of-Two-Clinical-Studies-in-ALS>