

NeuroSense Therapeutics Commences Enrollment and Dosing in its Pharmacokinetic Study of PrimeC for ALS

Study conducted under FDA cleared protocol in parallel with international Phase IIb trial expected to commence in Q2 2022

CAMBRIDGE, Mass., April 11, 2022 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (Nasdaq: NRSN) ("NeuroSense"), a company developing treatments for severe neurodegenerative diseases, today announced that it has enrolled and dosed the first healthy volunteer in its pharmacokinetic (PK) study ([NCT05232461](#)) of its lead combination drug candidate PrimeC developed for the treatment of amyotrophic lateral sclerosis (ALS).

The pharmacokinetic open-label, randomized, single-dose, three-treatment, three-period crossover study is evaluating the effect of food on the bioavailability of PrimeC as compared to the bioavailability of co-administered ciprofloxacin tablets and celecoxib capsules in 12 healthy adult subjects in the US under an FDA cleared IND protocol.

PrimeC is a novel extended-release oral formulation composed of a unique fixed-dose combination of two FDA-approved drugs, ciprofloxacin and celecoxib, and is designed to synergistically target several key mechanisms of ALS that contribute to motor neuron degeneration, inflammation, iron accumulation, and impaired RNA regulation to potentially inhibit the progression of ALS.

"We expect to complete and report data on this pharmacokinetic study in Q3 2022. The combined data from both the PK study and our upcoming Phase IIb study will assist in designing a pivotal Phase III trial of PrimeC for the treatment of ALS in alignment with FDA requirements," stated NeuroSense CEO Alon Ben-Noon.

About PrimeC

PrimeC was granted Orphan Drug Designation by the FDA and the European Medicines Agency (EMA). NeuroSense completed a Phase IIa clinical study which successfully met its safety and efficacy endpoints including reducing functional and respiratory deterioration and statistically significant changes in ALS-related biological markers indicating PrimeC's biological activity. The Company plans to initiate a Phase IIb double-blind placebo-controlled multinational study in Q2 2022 with an optimized dose and a unique upgraded formulation. Through a collaboration with Massachusetts General Hospital in Boston on novel Neuron-Derived Exosomes (NDEs), NeuroSense is working to further determine the biological changes in ALS-related pathologies and the effect of PrimeC on relevant targets. Results from this study are expected Q2 2022.

About ALS

Amyotrophic lateral sclerosis (ALS) is an incurable neurodegenerative disease that causes complete paralysis and death within 2-5 years from diagnosis. Every year, more than 5,000 patients are diagnosed with ALS in the US alone, with an annual disease burden of \$1 billion. The number of patients with ALS is expected to grow 24% by 2040 in the US and EU.

About NeuroSense

NeuroSense Therapeutics, Ltd. is a clinical-stage biotechnology company focused on discovering and developing treatments for patients suffering from debilitating neurodegenerative diseases. NeuroSense believes that these diseases, which include amyotrophic lateral sclerosis (ALS), Alzheimer's disease and Parkinson's disease, among others, represent one of the most significant unmet medical needs of our time, with limited effective therapeutic options available for patients to date. Due to the complexity of neurodegenerative diseases and based on strong scientific research on a large panel of related biomarkers, NeuroSense's strategy is to develop combined therapies targeting multiple pathways associated with these diseases.

For additional information, we invite you to visit our [website](#) and follow us on [LinkedIn](#) and [Twitter](#).


Forward-Looking Statements

This press release contains "forward-looking statements" that are subject to substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "target," "aim," "should," "will" "would," or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on NeuroSense Therapeutics' current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict and include statements regarding the company's PrimeC development program; the potential for PrimeC to safely and effectively target ALS; preclinical and clinical data for PrimeC; the timing of current and future clinical trials; the nature, strategy and focus of the company and further updates with

respect thereto; and the development and commercial potential of any product candidates of the company. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. Forward-looking statements contained in this announcement are made as of this date, and NeuroSense Therapeutics Ltd. undertakes no duty to update such information except as required under applicable law.

SOURCE NeuroSense

For further information: For further information: Email: info@neurosense-tx.com, Tel: +972 (0)9 799 6183

Additional assets available online:  [Photos \(1\)](#)

<https://neurosense.investorroom.com/2022-04-11-NeuroSense-Therapeutics-Commences-Enrollment-and-Dosing-in-its-Pharmacokinetic-Study-of-PrimeC-for-ALS>