

NeuroSense Receives Regulatory Approval to Commence Patient Enrollment in Italy for its Phase 2b Trial in ALS

CAMBRIDGE, Mass., Nov. 16, 2022 /[PRNewswire](#)/ -- NeuroSense Therapeutics Ltd. (NASDAQ: NRSN) ("NeuroSense"), a company developing treatments for severe neurodegenerative diseases, today announced it has received approval from the Italian Medicines Agency (AIFA) to commence patient enrollment in Italy for PARADIGM, the Company's Phase 2b clinical trial of its lead drug candidate PrimeC in the treatment of amyotrophic lateral sclerosis (ALS). PARADIGM is currently enrolling patients in Israel and recently received clearance from the U.S. Food and Drug Administration to open clinical sites for patient recruitment in the U.S. NeuroSense expects to enroll and dose the first patients in Italy and in the U.S. in the next few weeks.

The Phase 2b ([NCT05357950](#)) double-blind, placebo-controlled, multinational clinical trial aims to assess PrimeC's efficacy, as well as safety and tolerability, in people living with ALS. The study is enrolling and randomizing 69 people living with ALS in a 2:1 ratio to receive PrimeC or placebo, respectively. Study participants are allowed to continue standard of care (SOC) treatment of approved products. Primary endpoints of the study include assessment of ALS-biomarkers, evaluation of clinical efficacy, and improvement in quality of life. All subjects who complete the 6 month double-blind, placebo-controlled dosing period will be switched to the PrimeC active arm for a 12-month open label extension.

"Clearance from AIFA, Italy's health regulatory agency, is another important milestone achieved that supports our goal of providing patients in need from the EU, in addition to the US and other regions, the opportunity to join the PARADIGM study and receive PrimeC, which aims to target pertinent mechanisms in ALS with the hope for a meaningful clinical benefit." stated NeuroSense CEO Alon Ben-Noon.

About PrimeC

PrimeC, NeuroSense's lead drug candidate, is a novel extended-release oral formulation composed of a unique fixed-dose combination of two FDA-approved drugs: ciprofloxacin and celecoxib. PrimeC is designed to synergistically target several key mechanisms of amyotrophic lateral sclerosis (ALS) that contribute to motor neuron degeneration, inflammation, iron accumulation and impaired RNA regulation to potentially inhibit the progression of ALS. NeuroSense completed a Phase 2a 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. 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. PrimeC was granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

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 U.S. alone, with an annual disease burden of \$1 billion. The number of patients with ALS is expected to grow 24% by 2040 in the U.S. 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 patent applications; the company's PrimeC development program; the potential for PrimeC to safely and effectively target ALS; preclinical and clinical data for PrimeC; patients enrolling; 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.

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