NeuroSense Investor Relations

NeuroSense Enrolls First Patient in Phase IIb ALS Trial for its Combination Therapy PrimeC

- *Phase IIa study successfully met safety and efficacy endpoints including reducing functional and respiratory deterioration and statistically significant changes in ALS-related biomarkers*
- *PrimeC has Orphan Drug Designation with the FDA and EMA*

CAMBRIDGE, Mass., June 1, 2022 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (Nasdaq: NRSN) ("NeuroSense"), a company developing treatments for severe neurodegenerative diseases, today announced it has enrolled the first patient in its Phase IIb PARADIGM trial for its lead drug candidate PrimeC for the treatment of amyotrophic lateral sclerosis (ALS). PARADIGM will enroll 69 people living with ALS in Israel, Italy, and the U.S. The double blind, placebo controlled, multicenter trial will randomize participants at a 2:1 ratio to receive PrimeC or placebo, respectively. Clinical trial endpoints include assessment of ALS-biomarkers, evaluation of clinical efficacy, and improvement in quality of life to demonstrate an attenuation in disease progression. NeuroSense expects to complete enrollment by the end of 2022 and to report top-line results in Q2 2023.

PrimeC is a novel, patented formulation consisting of specific doses of two FDA-approved drugs, ciprofloxacin and celecoxib, designed to work synergistically on multiple targets by regulating microRNA synthesis, modulating iron accumulation, and reducing neuroinflammation. The Phase IIb study is designed to utilize an optimized dose and improved formulation which aims to maximize the synergistic effect between the compounds in the combination drug, relative to the formulation used in the prior Phase IIa study.

"As PrimeC enters this advanced stage trial, we are hopeful that our enhanced formulation will further improve on the promising results we observed from our combination therapy in our Phase IIa ALS study," stated NeuroSense's CEO, Alon Ben-Noon. "In this well-designed, patient-centric study, we are working in collaboration with cutting-edge technology partners on an extensive panel of biomarkers to elucidate PrimeC's mechanism of action, as we believe this could enable patient stratification and increase likelihood of success in a pivotal trail. Targeting multiple pathological pathways in ALS, synergistically, is a paradigm shift in ALS therapy".

About PrimeC

PrimeC, NeuroSense's lead drug candidate is a combination therapy that was granted Orphan Drug Designation by the U.S. Food and Drug Administration (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. 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 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 ourwebsite 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; the timing of enrolment, completion and reporting of results from 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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For further information: For further information: Email: info@neurosense-tx.com, Tel: +972 (0) 9 799 6183

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