NeuroSense Investor Relations

NeuroSense Receives FDA Clearance of IND for its ALS Phase 2b Study

- ***NeuroSense Therapeutics receives FDA clearance to commence patient enrollment in the U.S. with PrimeC, a novel combination therapy***
- ***Follows a successful U.S. pharmacokinetic (PK) study which confirmed PrimeC's favorable extended release properties***

CAMBRIDGE, Mass., Nov. 15, 2022 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (NASDAQ: NRSN) ("NeuroSense"), a company developing treatments for severe neurodegenerative diseases, today announced the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) to enroll patients in the U.S. for its Phase 2b PARADIGM study for its lead drug candidate PrimeC in the treatment of amyotrophic lateral sclerosis (ALS). PARADIGM is currently enrolling patients in Israel, and NeuroSense expects to open clinical sites for patient recruitment in the European Union in the coming weeks. PrimeC has Orphan Drug Designation with the FDA and the European Medicines Agency (EMA).

As a combination therapy of two FDA approved drugs with well-established safety profiles, PrimeC is designed to synergistically target several key ALS mechanisms that contribute to motor neuron degeneration, inflammation, iron accumulation, and impaired RNA regulation to potentially inhibit the progression of ALS.

PARADIGM, (NCT05357950), a Phase 2b 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 will be allowed to administer standard of care (SOC) treatment of approved products. Primary and secondary 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.

NeuroSense expects to enroll and dose the first U.S. patients in the next few weeks at leading ALS centers on both the east and west coast.

"FDA's acceptance of our IND paves the way for NeuroSense to commence patient enrollment in the U.S. and is another significant milestone achieved in our drug development plan," stated NeuroSense CEO Alon Ben-Noon. "This clinical trial is evaluating our new and improved extended release formulation of PrimeC, which may provide a better outcome than already observed in our prior Phase 2a study. We are pleased to offer PrimeC to patients who are eager to take part in the clinical program, and we look forward to completing enrollment and announcing results in the next several months - Mid 2023."

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; 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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