NeuroSense Investor Relations

NeuroSense Therapeutics Receives FDA Clearance of IND for PrimeC for the Treatment of ALS

- PrimeC, a novel combination therapy, demonstrated efficacy and safety in Phase IIa study
- Phase IIb study expected to commence Q2 2022

CAMBRIDGE, Mass., March 21, 2022 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (Nasdaq: NRSN) ("NeuroSense"), a company developing treatments for severe neurodegenerative diseases, today announced that it has received clearance from the U.S. Food and Drug Administration (FDA) to initiate a pharmacokinetic study of PrimeC in healthy adult subjects. PrimeC 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.

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.

The pharmacokinetic study (NCT05232461) is a Phase I open-label, randomized, single-dose, three treatment, three-period crossover study to evaluate 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.

"Data from our Phase IIa clinical study confirmed that PrimeC is a novel therapy with the potential to help people with ALS and address a $3 billion market in need of a more effective treatment," stated NeuroSense CEOAlon Ben-Noon. "As we prepare to initiate our Phase IIb study in the next few months, the goal of our pharmacokinetic study under FDA IND is to generate additional data on the bioavailability of PrimeC as it relates to food intake in healthy individuals. We are deeply committed to improving the lives of people with ALS and are proud to develop a new potential treatment to address this complex disease."

NeuroSense recently announced the third stage of its collaboration with Massachusetts General Hospital in Boston on novel Neuron-Derived Exosomes (NDEs) 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.

NeuroSense is also advancing programs in Alzheimer's disease for its drug candidate CogniC and Parkinson's disease for StabiliC. Data from preclinical studies are expected H2 2022, and following an IND submission to the FDA, NeuroSense expects to initiate clinical studies in these indications in H1 2023.

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 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 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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