NeuroSense Investor Relations

NeuroSense Completes Dosing of Last Patient in the Double-Blind Segment of Phase 2b ALS Trial: Topline Clinical Efficacy Results Expected December 2023

- ***Clinical efficacy results (secondary endpoints) and safety results (primary endpoints) expectedDecember 2023***
- ***Biogen collaboration biomarker results expected Q1 2024***
- ***Primary biomarker endpoints to be reported H1 2024***

CAMBRIDGE, Mass., Nov. 6, 2023 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (Nasdaq: NRSN) ("NeuroSense"), a company developing treatments for severe neurodegenerative diseases, today announced it has completed dosing of the last patient in the double-blind segment of its Phase 2b amyotrophic lateral sclerosis (ALS) trial of PrimeC (PARADIGM). PrimeC is designed to synergistically target several key ALS mechanisms that contribute to motor neuron degeneration, inflammation, iron accumulation, and impaired RNA regulation to inhibit the progression of ALS. PrimeC has been granted Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

Sixty-nine people living with ALS inCanada, Italy, and Israel were enrolled in the double-blind segment of PARADIGM (NCT05357950), a multinational, randomized, double-blind, placebo-controlled Phase2b clinical trial of PrimeC in ALS, wherein trial participants were dosed for 6 months after being randomized 2:1 to receive PrimeC or placebo, respectively. After completion of the double-blind segment, the participants had the option to enroll in a 12-month open label extension (OLE), during which they all receive treatment with PrimeC. 96% of the participants chose to continue into the OLE.

The Company expects to release clinical efficacy results (secondary endpoints) from the double-blind segment of the trial in December 2023. These secondary endpoints include clinical outcome measures: Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R), Slow Vital Capacity (SVC), quality of life and overall survival. ALSFRS-R is recognized and widely used as an endpoint in ALS clinical trials that are evaluated by the FDA. This scale aids in providing a measurement of the impact of the disease on various functional activities and the overall quality of life of patients with ALS. The Company also expects to report the safety and tolerability results (primary endpoints) of the double-blind segment of the trial in December 2023.

The Company expects to report on another primary endpoint, the assessment of ALS-biomarkers, TDP-43 and Prostagladin2, to evaluate PrimeC's biological activity, in H1 2024 following the completion of the ongoing analysis of patients' plasma. PrimeC was previously observed to have a statistically significant impact in TDP-43 and Prostagladin2, in NeuroSense's previous Phase 2a trial.

Additionally, in the first quarter of 2024, the Company expects to report results from a strategic collaboration with Biogen that is evaluating the impact of PrimeC on patients enrolled in PARADIGM. Under this collaboration, Biogen is to meaningful biomarker analysis and upon receipt of results, has the right of first refusal to co- fund this develop/commercialize PrimeC for the treatment of ALS for a limited time following the results.

Recent findings from independent studies at the University of Southern California showed PrimeC significantly increased the survival rate of induced motor neurons in an *in vitro* ALS study and PrimeC performed among the best in improving motor neuron survival when compared to several other ALS drugs in development and two U.S. FDA approved ALS drugs.

"We are excited to soon begin sharing the results of the double-blind segment of our Phase2b trial," stated Alon Ben Noon, CEO of NeuroSense. "We would like to thank the trial participants, their caregivers and families, as well as the sites' Principal Investigators and study coordinators for their tremendous contribution to PARADIGM."

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 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 trial which 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. PrimeC was granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

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 the timing for release of results from the double-blind segment of the Company's Phase 2b trial, the timing for release of results from the Company's strategic collaboration with Biogen, the timing for release of additional results from PARADIGM clinical trial, the cash runway of the Company, the timing of a Phase 2 trial for Alzheimer's disease and patient enrollment regarding a Phase 3 pivotal ALS trial of PrimeC. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. The future events and trends may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward looking statements. These risks include unexpected R&D costs or operating expenses, a delay in the reporting of clinical top-line results from PARADIGM clinical trial, a delay in patient enrollment for a Phase 2 trial for Alzheimer's disease or its planned Phase 3 pivotal ALS trial of PrimeC; the potential for PrimeC to safely and effectively target ALS; preclinical and clinical data for PrimeC; the timing of current and future clinical trials, timing for reporting data; the development and commercial potential of any product candidates of the company; and other risks and uncertainties set forth in NeuroSense's filings with the Securities and Exchange Commission (SEC)., You should not rely on these statements as representing our views in the future. More information about the risks and uncertainties affecting the Company is contained under the heading "Risk Factors" in the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 22, 2023. 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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