NeuroSense Investor Relations

NeuroSense Announces Completion of PARADIGM Study Highlighting PrimeC's Significant Efficacy and Survival Benefits in ALS

- ***In participants who received PrimeC from the start of the 18-month study compared to those initially on placebo before transitioning to PrimeC, disease progression was slowed by 33% (p=0.007), demonstrated in a 58% improvement in survival rates***
- ***Consistent data across subgroups underscore the potential of PrimeC to redefine the standard of care in the treatment of ALS***

CAMBRIDGE, Mass., Dec. 4, 2024 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (Nasdaq: NRSN) ("NeuroSense"), a late-clinical stage biotechnology company developing novel treatments for severe neurodegenerative diseases, is pleased to announce today statistically significant positive results from the 18-month data analysis of the PARADIGM study, evaluating the efficacy of PrimeC in the treatment of Amyotrophic Lateral Sclerosis (ALS). These results highlight a significant improvement in ALS Functional Rating Scale-Revised (ALSFRS-R) scores and survival rates for patients receiving PrimeC from the start compared to those who started on placebo.

The 18-month PARADIGM study results will be presented at the 2024 International Symposium on ALS/MND, taking place December 6-8, 2024, in Montreal, Canada, by Prof. Merit Cudkowicz, Chair of Neurology at Massachusetts General Hospital, Director of the Sean M. Healey & AMG Center for ALS, and the Julieanne Dorn Professor of Neurology at Harvard Medical School. Prof. Cudkowicz is a world-renowned leader in ALS research, whose insights into PrimeC's potential to improve patient outcomes are highly anticipated.

Additional results will be shared in due course.

The Company anticipates to update on the outcome of the meeting with the FDA in the next several days.

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 people are diagnosed with ALS in the U.S. alone, with an annual disease burden of $1 billion. The number of people living with ALS is expected to grow by 24% by 2040 in the U.S. and EU.

About ALSFRS-R
Disease progression is measured by the ALS Functional Rating Scale-Revised (ALSFRS-R), which is the most widely used ALS tracking tool accepted by the FDA, utilized by neurologists treatingALS patients, in clinical trials, and by other regulators to determine disease progression. It tracks 12 changes in a person's physical abilities over time including functions such as: speech, walking, climbing stairs, dressing/hygiene, handwriting, turning in bed, cutting food, salivation, swallowing, and breathing. A single point change on the ALSFRS-R has a significant impact on ALS patients, such as the transition from independent feeding to requiring assistance or independent breathing to needing to use a machine ventilator.

About PARADIGM
PARADIGM is a prospective, multinational, randomized, double-blind, placebo-controlled Phase2b (NCT05357950) clinical trial of PrimeC in ALS. The trial included 68 participants living with ALS in Canada, Italy, and Israel.

As previously reported, in the 12 months readout, the study revealed a remarkable difference of 6.5 points in the ALS Functional Rating Scale-Revised (ALSFRS-R) between the group treated with PrimeC for 12 months and the group that received placebo for 6 months before transitioning to PrimeC. This represents a 36% improvement, with a highly significant P value of 0.009. These outcomes mark the best results ever achieved in ALS clinical research.
Most patients enrolled in both the active and placebo arms of the trial were concurrently treated with Riluzole, the ALS standard of care medication, indicating PrimeC slowed disease progression well beyond the level afforded by the FDA approved ALS drug.

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 ALS that contribute to motor neuron degeneration, inflammation, iron accumulation and impaired ribonucleic acid ("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 and the European Medicines Agency.

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, YouTube and X. Information that may be important to investors may be routinely posted on our website and these social media channels.

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 of regulatory filings, meetings and regulatory decisions. 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 the risk of a delay in submission by the Company of its regulatory dossier, that regulatory approvals for PrimeC will be delayed or not obtained in Canada or elsewhere; unexpected R&D costs or operating expenses, insufficient capital to complete development of PrimeC, a delay in the reporting of additional results from PARADIGM clinical trial, the timing of expected regulatory and business milestones, risks associated with meeting with the FDA and Health Canada to determine the best path forward following the results from PARADIGM clinical trial, including a delay in any such meeting; the potential for PrimeC to safely and effectively target ALS; preclinical and clinical data for PrimeC; the uncertainty regarding outcomes and the timing of current and future clinical trials; timing for reporting data; the development and commercial potential of any product candidates of Neurosense; the ability of NeuroSense to remain listed on Nasdaq; 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 NeuroSense is contained under the heading "Risk Factors" in the Annual Report on Form 20-F filed with the Securities and Exchange Commission on April 4, 2024 and NeuroSense's subsequent filings with the SEC. Forward-looking statements contained in this announcement are made as of this date, and NeuroSense undertakes no duty to update such information except as required under applicable law.

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