NeuroSense Investor Relations

NeuroSense Demonstrates Statistically Significant Efficacy and Survival Benefits in People Living with ALS: The Promising Results from the 12-Month PARADIGM Study Highlight PrimeC's Potential as a Disease Modifying Drug

- ***Disease progression was slowed by 36% (p=0.009) in participants who received PrimeC for 12 months compared to those who initially received a placebo***
- ***Consistent data across multiple endpoints underscore the potential of PrimeC to redefine the ALS treatment paradigm***
- ***NeuroSense planning for Phase 3 clinical study in the U.S. andEurope***

CAMBRIDGE, Mass., July 1, 2024 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (NASDAQ: NRSN) ("NeuroSense"), a late-clinical stage biotechnology company developing novel treatments for severe neurodegenerative diseases, today reported statistically significant results from the 12-month data analysis of the PARADIGM Phase 2b study evaluating PrimeC in people living with Amyotrophic Lateral Sclerosis (ALS).

The data show a significant improvement in the rate of decline of ALS Functional Rating Scale-Revised (ALSFRS-R) scores and survival rates for subjects who received PrimeC from the start of the trial compared to those who started on placebo. Specifically, the intent to treat (ITT) analysis of the study at 12 months revealed a difference of 6.5 points in the ALSFRS-R, which represents a 36% improvement and a highly statistically significant P value of 0.009.

In addition, at 12 months participants on PrimeC demonstrated better survival than those initially on placebo, by 43%.

In an additional pre-defined analysis of the Per-Protocol Population at 12 months, the results showed an even greater effect, with a difference of approximately 7.7 points (p=0.003) between the groups, translating to more than 40% improvement for participants who received PrimeC from the start compared to those on placebo. Furthermore, this analysis indicated that the survival rate of participants on PrimeC improved by 63% compared to participants who received a placebo.

"These exciting long-term results demonstrate how study participants experienced more slowing of progression over time with PrimeC as measured against ALSFRS-R, which is the current gold-standard scale used in ALS drug development," said Merit Cudkowicz, M.D., M.Sc., chair of neurology and Director of the Sean M. Healey & AMG Center for ALS at Massachusetts General Hospital. "The need for new treatments for people living with ALS has never been greater. PrimeC has great potential based on its mode of action and the phase 2 trial results and warrants further evaluation in a Phase 3 trial in an expeditious manner."

Vivian Drory, MD, Head of the ALS clinic at Tel-Aviv Sourasky Medical Center, added: "The promising results from the 12-month PARADIGM study highlight the significant potential of PrimeC as a disease-modifying drug for ALS. These findings underscore the importance of early intervention, which can lead to more substantial benefits, and provide valuable insights that will inform the design of the Company's Phase 3 study, increasing the likelihood of success."

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 treating ALS 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. 96% of the trial participants who completed the 6-month double-blind portion of the trial chose to receive treatment with PrimeC through a 12-month open label extension. Furthermore, to date (June 2024) all participants that completed the 18-month trial treatment duration, requested to continue PrimeC, which is provided to them in an Investigator Initiated Trial, not limited with time.

As previously reported, in the 6-month double-blind segment of the trial, the data showed clinically meaningful signs of efficacy with a 29% difference in favor of PrimeC vs placebo in analysis of the intent to treat (ITT) population. In the PP top-line analysis from PARADIGM, a statistically significant slowing of disease progression was observed with a 37.4% (p=0.03) difference in ALSFRS-R in favor of PrimeC vs placebo. 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 PrimeC as a potential treatment for people with ALS. 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 additional results from PARADIGM clinical trial, the timing of expected regulatory and business milestones, risks associated with meeting with the FDA 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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