

NeuroSense Therapeutics Announces Acceptance of Two PrimeC Abstracts at the 2024 NEALS Annual Meeting

CAMBRIDGE, Mass., Oct. 7, 2024 /PRNewswire/ -- [NeuroSense Therapeutics Ltd.](#) (Nasdaq: NRSN) ("NeuroSense"), a late-clinical stage biotechnology company developing novel treatments for severe neurodegenerative diseases, today announced the acceptance of two abstracts focusing on the company's lead drug candidate, PrimeC, for the treatment of Amyotrophic Lateral Sclerosis (ALS). These abstracts will be presented at the 2024 Annual Northeastern Amyotrophic Lateral Sclerosis (NEALS) Consortium Meeting, taking place October 21 to October 24 in Clearwater, Florida.

The abstracts will highlight groundbreaking data from NeuroSense's Phase2b PARADIGM study. The first abstract, presenting clinical outcomes, will be delivered by renowned clinician Dr. Merit Cudkowicz, Chief of Neurology at Massachusetts General Hospital (MGH) and Director of the Sean M. Healey & AMG Center for ALS, USA. The second abstract, focused on biomarker analysis, will be presented by Dr. Cristian Lunetta, a leading neurologist and ALS specialist from the NEuroMuscular Omnicentre (NEMO) in Milan, Italy.

These presentations underscore NeuroSense's commitment to driving forward ALS research and the development of innovative treatments for this devastating disease. The company's recent findings demonstrated that PrimeC reduced disease progression by **36% reduction in disease progression (p=0.009)** and a **43% improvement in survival rates** compared to placebo, further solidifying PrimeC's potential as a breakthrough therapy for ALS.

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 our [website](#) 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, 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 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 and 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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