NeuroSense Investor Relations

NeuroSense Receives Positive FDA Feedback on Phase 3 Study Design for PrimeC

- ***The Type C meeting with the FDA, combined with the recent 18-month Phase2b PARADIGM study readout, has the Company on track to commence a Phase 3 study in mid-2025***
- ***PrimeC has already demonstrated a significant impact on slowing disease progression and increasing survival rates in people living with ALS***

CAMBRIDGE, Mass., Dec. 11, 2024 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (NASDAQ: NRSN) ("NeuroSense"), a late-clinical stage biotechnology company developing novel treatments for severe neurodegenerative diseases, today announced it has concluded a Type C meeting with the U.S. Food and Drug Administration (FDA) for PrimeC in the treatment of amyotrophic lateral sclerosis (ALS). The purpose of the meeting was to discuss the design of a proposed Phase 3 clinical study and the plan for submission of an eventual 505(b)(2) marketing application. The Company had a productive discussion with the FDA regarding the design of the planned Phase 3 pivotal study with PrimeC, including efficacy and safety measurements.

The FDA's positive feedback and guidance on overall trial design marks a noteworthy achievement for NeuroSense, as alignment on the design is a critical step in enabling the study to meet regulatory expectations and potentially provide sufficient data for the drug's approval.

In light of the FDA's feedback, NeuroSense plans to submit a final protocol to the FDA during the first half of 2025 with the aim of commencing enrollment of the pivotal Phase 3 study in mid-2025, which would include approximately 300 patients divided by a ratio of 2:1, PrimeC to placebo. The Phase 3 study is expected to be a randomized, multi-center, multinational, prospective, double-blind, placebo-controlled study, with an open label extension (OLE), to evaluate the efficacy and safety of PrimeC in people living with ALS. Following 12 months of treatment, it is expected that all participants will transition to PrimeC for a 12-month OLE.

"The feedback from the FDA regarding our clinical strategy for the planned pivotal Phase 3 study and the plan for submission of an eventual marketing application, represents a significant milestone in our drug development program. It validates the progress we've made and reinforces our commitment to advancing a potential therapeutic option for people living with ALS, whose need for innovative treatments is urgent. This step brings us closer to delivering a much-needed solution to the ALS community," stated Alon Ben-Noon, CEO of NeuroSense.

NeuroSense has already completed PARADIGM (NCT05357950), a multinational, randomized, double-blind, placebo-controlled Phase 2b clinical trial of PrimeC in 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 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.

During the first 6 months of the trial, 45 participants were randomized to receive PrimeC, and 23 participants were randomized to receive placebo. This was followed by a 12-month open-label extension with all participants receiving PrimeC in a blinded manner, where neither the participants nor the clinical staff were aware of the initial treatment allocation.

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 submission of regulatory submissions to the FDA and the timing of commencement of enrollment for clinical trials, if any, and anticipated trial design. 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 commencement of enrollment for the Phase 3 trial, if any, or a delay in regulatory submissions with the FDA, the risk that the trial will not be completed, meet regulatory expectations or provide sufficient data for drug approval, unexpected changes in trial design, delay in submission by the Company of its regulatory dossier, that regulatory approvals for PrimeC will be delayed or not obtained in the U.S., Canada or elsewhere; unsuccessful results of the Phase 3 trial, 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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