NeuroSense Investor Relations

NeuroSense Completes Enrollment in Phase 2b ALS Clinical Trial

- ***96% of participants who completed the trial opted to receive treatment with PrimeC in a 12-month open label extension***
- ***Topline results expected Q4 2023***

CAMBRIDGE, Mass., May 15, 2023 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (Nasdaq: NRSN) ("NeuroSense"), a company developing treatments for severe neurodegenerative diseases, today announced the completion of enrollment in PARADIGM, a multinational, randomized, double-blind, placebo-controlled Phase 2b clinical trial of PrimeC in people living with amyotrophic lateral sclerosis (ALS). Study participants are dosed for 6 months after being randomized 2:1 to receive PrimeC or placebo, respectively, followed by a 12-month open label extension (OLE) phase, during which they receive PrimeC. NeuroSense anticipates topline results in Q4 2023. The study enrolled 69 participants living with ALS in Israel, Italy, and Canada. PrimeC has Orphan Drug Designation with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

As a novel combination therapy of two FDA approved drugs, celecoxib and ciprofloxacin, with well-established safety profiles, PrimeC is designed to synergistically target several key ALS mechanisms that contribute to motor neuron degeneration, inflammation, iron accumulation, and impaired RNA regulation to potentially inhibit the progression of ALS.

The primary efficacy endpoint of PARADIGM, (NCT05357950), is the assessment of ALS-biomarkers to evaluate PrimeC and its biological activity. Secondary endpoints include the clinical outcome measures Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R), Slow Vital Capacity (SVC), and overall survival, as well as safety and tolerability, in addition to a robust battery of additional biomarkers including neurofilaments.

Participants have the option to enroll in a 12-month OLE phase, during which they receive PrimeC. To date, 26 participants completed the 6-month double-blind phase of the trial and 25 of them chose to continue into the OLE. The results of the Phase 2b PARADIGM clinical trial will inform the design of a future pivotal Phase 3 clinical trial of PrimeC.

"It is highly encouraging that nearly all participants who completed the study have elected to continue in the OLE phase with the treatment of PrimeC," stated Prof. Vivian Drory, Principal Investigator of the PARADIGM trial at Tel Aviv Sourasky Medical Center. "We look forward to seeing the topline data from this study which uses an optimized formulation of PrimeC. Based on the new formulation, we are aiming for efficacy and safety results that will meet and exceed the results achieved in the Phase 2a study which was conducted here at Sourasky Medical Center."

"PARADIGM is tracking 17 different outcome measures while the primary endpoint remains focused on biomarkers. This wealth of outcome data will not only be used to optimize the design of a future pivotal Phase 3 study for PrimeC, but we believe it will provide greater insight into the mechanisms of ALS for the scientific community as we advance toward a day when ALS will become a highly treatable disease," stated NeuroSense's Chief Medical Officer, Dr. Ferenc Tracik.

"We are pleased to share this milestone for the PARADIGM clinical trial," stated NeuroSense's CEO, Alon Ben-Noon. "We are grateful to the participants living with ALS, their families, and the study investigators for their commitment to the PARADIGM trial and for taking part in our mission to develop an effective 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 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 study which successfully 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 our website 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 of top-line results of, and the results of, the PARADIGM clinical trial. Further, forward-looking statements are subject to a number of risks and uncertainties as a result of which actual results could differ materially and adversely from those anticipated or implied in the forward looking statements. These risks include a delay in the reporting of top-line results from PARADIGM clinical trial, the risk that the results of the trial will not be as anticipated, risks relating to patent applications; the company's PrimeC development program; the potential for PrimeC to safely and effectively target ALS; preclinical and clinical data for PrimeC; the timing of current and future clinical trials; the nature, strategy and focus of the company and further updates with respect thereto; and the development and commercial potential of any product candidates of the company as well as the risks 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.

Logo - https://mma.prnewswire.com/media/2076988/PARADIGM.jpg
Logo - https://mma.prnewswire.com/media/1707291/NeuroSense_Therapeutics.jpg

SOURCE NeuroSense

For further information: For further information: Email: info@neurosense-tx.com, Tel: +972 (0)9 799 6183

Additional assets available online: Photos (2)

https://neurosense.investorroom.com/2023-05-15-NeuroSense-Completes-Enrollment-in-Phase-2b-ALS-Clinical-Trial