NeuroSense Investor Relations

NeuroSense Receives U.S. FDA Confirmation of CMC Strategy for PrimeC in Preparation for Pivotal Phase 3 in ALS and Commercial Readiness

- ***Clinical efficacy top-line results of PARADIGM, a Phase 2b trial in ALS, expected in December 2023***

CAMBRIDGE, Mass., Nov. 13, 2023 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (NASDAQ: NRSN) ("NeuroSense"), a company developing treatments for severe neurodegenerative diseases, today announced it has concluded a successful Type D meeting with the U.S. Food and Drug Administration (FDA) for PrimeC in the treatment of amyotrophic lateral sclerosis (ALS). FDA Type D meetings are focused on a narrow set of issues at key decision points to provide timely feedback critical to move a drug development program forward. The purpose of NeuroSense's meeting with the FDA was to discuss PrimeC's chemistry, manufacturing, and controls (CMC) development plans in advance of an expected Phase 3 pivotal study and potential subsequent marketing approval. The FDA agreed with NeuroSense's proposed CMC development plan. PrimeC has already been granted Orphan Drug Designation by the FDA and the European Medicines Agency (EMA).

"This confirmation from the FDA of our CMC strategy for a future pivotal Phase 3 clinical trial and commercial launch of PrimeC in the treatment of ALS marks a critical milestone in our drug development program. It sets the stage for a smooth transition, particularly as we anticipate clinical efficacy top-line results (secondary endpoints) from our Phase 2b trial very soon," stated Alon Ben-Noon, CEO of NeuroSense.

NeuroSense is currently conducting PARADIGM (NCT05357950), a multinational, randomized, double-blind, placebo-controlled Phase 2b clinical trial of PrimeC in ALS. Sixty-nine people living with ALS in Canada, Italy, and Israel have been enrolled into PARADIGM, which aims to assess PrimeC's efficacy, as well as safety and tolerability. Primary and secondary endpoints of the study include assessment of ALS-biomarkers, evaluation of clinical efficacy, and improvement in quality of life. In the double-blind segment trial participants were dosed for 6 months after being randomized 2:1 to receive PrimeC or placebo, respectively. After completion of the double-blind segment, the participants had the option to enroll in a 12-month open label extension (OLE), during which they all receive treatment with PrimeC. 96% of the participants chose to continue into the OLE.

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. 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 for release of results from the double-blind segment of the Company's Phase 2b trial and regarding an expected Phase 3 pivotal study. 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 a delay in the reporting of clinical top-line results from PARADIGM clinical trial, the failure to meet the primary or secondary endpoints of the trial, a delay in patient enrollment for a Phase 2 trial for Alzheimer's disease or its planned Phase 3 pivotal ALS trial of PrimeC; the potential for PrimeC to safely and effectively target ALS; preclinical and clinical data for PrimeC; the timing of current and future clinical trials, timing for reporting data; the development and commercial potential of any product candidates of the company; 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 the Company is contained 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.

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