NeuroSense Investor Relations

NeuroSense Expands its Phase 2b ALS PARADIGM Trial to Canada and Withdraws Protocol from U.S. IND to Align its Clinical Strategy with the FDA for a Potential Pivotal Phase 3 Study

- ***Receives regulatory approval from Health Canada to commence enrollment***
- ***PARADIGM topline read-out expected H2 2023***

CAMBRIDGE, Mass., Feb. 6, 2023 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (NASDAQ: NRSN) ("NeuroSense"), a company developing treatments for severe neurodegenerative diseases, today announced that Health Canada approved the commencement of patient enrollment in Canada for the Company's Phase 2b PARADIGM study of its combination therapy PrimeC for the treatment of amyotrophic lateral sclerosis (ALS). Currently, over 50% of patients have been enrolled in PARADIGM with topline results expected in the second half of 2023.

Dr. Christen Shoesmith, Medical Director of the London Health Sciences Centre ALS Clinic and Principal Investigator of the PARADIGM trial in Canada, commented, "We are very pleased with Health Canada's approval to recruit and dose people living with ALS in the PARADIGM study. Canada is at the forefront of advancing promising treatments to provide much needed options for people living with ALS."

The U.S. Food and Drug Administration (FDA) requested additional non-clinical data from NeuroSense to support the duration of the PARADIGM trial, as PrimeC is intended for long-term administration for the treatment of ALS. As a result, and following alignment with the agency on this subject, NeuroSense and the FDA have agreed that NeuroSense will withdraw its study protocol from the Investigational New Drug application (IND). NeuroSense is planning a formal meeting with the FDA to align its clinical and regulatory strategy for a potential pivotal Phase 3 trial that is intended to support a New Drug Application (NDA) submission, pending the successful conclusion of the PARADIGM trial.

"Our North American clinical development strategy got a boost from Health Canada, which approved our Phase 2b PARADIGM study to dose patients," stated NeuroSense CEO Alon Ben-Noon. "In the interest of treating and completing dosing of people living with ALS in an expedient and safe manner through PARADIGM, we've focused our North American recruitment in Canada. We look forward to working with the FDA on a path that includes clinical sites in the U.S. in a future Phase 3 pivotal study of PrimeC to address the dire unmet need of the U.S. ALS community who are eager to receive PrimeC for long term use."

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 IIa 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. Through a collaboration with Massachusetts General Hospital in Boston on novel Neuron-Derived Exosomes (NDEs), NeuroSense is working to further determine the biological changes in ALS-related pathologies and the effect of PrimeC on relevant targets. PrimeC was granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

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 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 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 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. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. Such risks and uncertainties include the risk that there will a delay in the timing of the report of topline results of PARADIGM and other risks and uncertainties set forth in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 20-F filed with the SEC on April 14, 2022. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. 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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