NeuroSense Investor Relations

NeuroSense Receives Approval in Germany to Enroll Patients in its Phase 2b ALS Trial

- ***PARADIGM protocol is approved in four countries:Israel, Italy, Canada, and Germany***
- ***Topline results expected in H2 2023***

CAMBRIDGE, Mass., Feb. 8, 2023 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (NASDAQ: NRSN) ("NeuroSense"), a company developing treatments for severe neurodegenerative diseases, today announced that Germany's Federal Institute for Drugs and Medical Devices (BfArM) approved the Company's Clinical Trial Application (CTA) to enroll patients in PARADIGM, its Phase 2b study of its lead combination drug candidate PrimeC in the treatment of amyotrophic lateral sclerosis (ALS).

PARADIGM is a Phase 2b randomized, multi-center, multinational, prospective, double-blind, placebo-controlled study, with an open-label extension, to evaluate the safety, tolerability, and efficacy of PrimeC. To date, over 50% of the planned 69 study participants have been enrolled.

"We expect to enroll the first study participant inGermany in the next few weeks, and we are very pleased to receive regulatory clearance to enroll and dose people living with ALS also in Germany for our PARADIGM study," stated NeuroSense's Chief Medical Officer, Dr. Ferenc Tracik. "We are currently on track to complete enrollment and report data in the second half of this year."

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. 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 enrollment of the study participants in,

and the report of topline results of, the PARADIGM study 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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For further information: For further information: Email: info@neurosense-tx.com, Tel: +972 (0)9 799 6183

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