NeuroSense Investor Relations

NeuroSense Receives FDA Clearance to Initiate Pivotal Phase 3 Trial for PrimeC in ALS

CAMBRIDGE, Mass., Nov. 24, 2025 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (Nasdaq: NRSN) ("NeuroSense"), a late-clinical stage biotechnology company developing novel treatments for severe neurodegenerative diseases, today announced that the U.S. Food and Drug Administration (FDA) has completed the review of the Investigational New Drug (IND) amendment application and authorized the Company to initiate the pivotal Phase 3 clinical trial for the evaluation of its lead drug candidate, PrimeC, for the treatment of amyotrophic lateral sclerosis (ALS).

With the FDA's clearance, NeuroSense is preparing for trial initiation and aims to have its first patient enrolled in the coming months upon securing the strategic resources needed to launch the trial.

The global pivotal Phase 3 trial, PARAGON, is powered at over 95% to achieve its primary endpoint and to expand upon the results of NeuroSense's Phase 2b PARADIGM trial, which demonstrated promising clinical and biomarker outcomes and a favorable safety and tolerability profile.

"This FDA clearance marks a meaningful advancement for NeuroSense and for people living with ALS. We believe this progress lays a strong foundation for additional achievements across several fronts in the near future," stated Alon Ben-Noon, Chief Executive Officer of NeuroSense. "We recognize the significant unmet need of people living with ALS and remain committed to delivering a meaningful therapy through our efforts."

Based on prior successful discussions with the FDA and in line with its recent comments and recommendations, PARAGON is expected to be conducted in the U.S. and EU and include 300 people living with ALS randomized in a ratio of 2:1 (PrimeC : Placebo). The prospective, double-blind, 12-month placebo-controlled trial, has an open label extension to evaluate safety and efficacy of PrimeC. The trial will employ an adaptive design allowing for interim analyses to optimize sample size and assess early efficacy and futility boundaries.

Additional details regarding the PARAGON trial design and timelines will be provided in NeuroSense's upcoming investor webinar on December 8th, 2025 and on NeuroSense's website. Registration to the webinar is availablehere.

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 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 and Alzheimer's Disease (AD) that contribute to motor neuron degeneration, inflammation, iron accumulation and impaired ribonucleic acid ("RNA") regulation to potentially inhibit the progression of ALS and AD.

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 commencement of the Phase 3 trial. 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 that the Phase 3 trial for PrimeC in ALS will not occur, or if it occurs, will be delayed; that the trial will not be successful; uncertainty regarding outcomes and the timing of current and future clinical trials; timing for reporting data; 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 7, 2025 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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Additional assets available online: Photos (1)

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