NeuroSense Investor Relations

NeuroSense Therapeutics Enters Binding Term Sheet to Advance PrimeC for ALS

- **Binding Term Sheet with a leading global pharmaceutical company includes a substantial upfront payment and funding for the Phase 3 study**
- **Additionally, milestone payments and double-digit royalties on annual net sales**
- **The transaction is subject to finalization of a definitive agreement, anticipated in Q1 2025**

CAMBRIDGE, Mass., Dec. 23, 2024 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (Nasdaq: NRSN) ("NeuroSense"), a late-clinical stage biotechnology company developing novel treatments for severe neurodegenerative diseases, announced today that it has entered into a binding term sheet with a leading global pharmaceutical company to advance the development and commercialization of PrimeC, its proprietary treatment drug for amyotrophic lateral sclerosis (ALS) in certain key territories. NeuroSense would retain full rights to PrimeC in other key territories.

The binding term sheet outlines substantial financial terms from the pharmaceutical company, including:

- A substantial upfront payment upon signing a definitive agreement,
- Funding for the Phase 3 clinical trial,
- Regulatory and net sales milestone payments, and
- A tiered royalty structure reaching double-digit percentage on annual net sales.

The binding term sheet is subject to finalization of a definitive agreement, anticipated in the first quarter of 2025.

The pharmaceutical company would have an exclusive license to distribute, market, promote, sell and develop PrimeC for ALS in certain key markets, and non-exclusive rights for research and manufacturing for PrimeC for ALS, subject to terms and conditions in the definitive agreement.

PrimeC is a proprietary fixed-dose combination of two FDA-approved drugs, uniquely formulated to enhance bioavailability and provide synergistic effects that target multiple ALS disease pathways. Results from NeuroSense's Phase 2b PARADIGM clinical trial demonstrated positive safety and efficacy, strengthening confidence in its potential to address the urgent unmet medical need in 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 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 PARADIGM

PARADIGM is a prospective, multinational, randomized, double-blind, placebo-controlled Phase2b (NCT05357950) clinical trial of PrimeC in ALS. The trial included 68 participants living with ALS in Canada, Italy, and Israel.

During the first 6 months of the trial, 45 participants were randomized to receive PrimeC, and 23 participants were randomized to receive placebo. This was followed by a 12-month open-label extension with all participants receiving PrimeC in a blinded manner, where neither the participants nor the clinical staff were aware of the initial treatment allocation.

Most patients enrolled in both the active and placebo arms of the trial were concurrently treated with Riluzole, the ALS standard of care medication, indicating PrimeC slowed disease progression well beyond the level afforded by the FDA approved ALS drug.

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 that contribute to motor neuron degeneration, inflammation, iron accumulation and impaired ribonucleic acid ("RNA") regulation to potentially inhibit the progression of ALS. NeuroSense completed a Phase 2a clinical trial which 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 and the European Medicines Agency.

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 the terms of license and timing of a definitive agreement or if a definitive agreement is executed at all. 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 a definitive agreement of the license to the global pharmaceutical company will be delayed or not executed at all, or that, if executed, it will not be on terms described above, the risk that contemplated license agreement, if executed, will not lead to the current anticipated benefits to NeuroSense, the risk of a delay in submission by the Company of its regulatory dossier, that regulatory approvals for PrimeC will be delayed or not obtained in Canada or elsewhere; unexpected R&D costs or operating expenses, insufficient capital to complete development of PrimeC, a delay in the reporting of additional results from PARADIGM clinical trial, the timing of expected regulatory and business milestones, risks associated with meeting with the FDA and Health Canada to determine the best path forward following the results from PARADIGM clinical trial, including a delay in any such meeting; the potential for PrimeC to safely and effectively target ALS; preclinical and clinical data for PrimeC; the uncertainty regarding outcomes and the timing of current and future clinical trials; timing for reporting data; the development and commercial potential of any product candidates of Neurosense; 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 4, 2024 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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