

NeuroSense Therapeutics Announces Successful Completion of Commercial Manufacturing Scale-Up for PrimeC in Preparation for Potential Canadian Market Launch

NeuroSense Announces Global CDMO Selection and Manufacturing Scale-Up, Enabling Rapid Pathway to Commercialization for What is Projected to be a \$100-150M Canadian Market Opportunity

CAMBRIDGE, Mass., May 7, 2025 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (NASDAQ: NRSN) ("NeuroSense"), a late-stage clinical biotechnology company developing novel treatments for severe neurodegenerative diseases, today announced that it has successfully scaled-up its production of PrimeC to commercial scale, marking a significant step toward bringing this potential disease-modifying ALS therapy to patients, following the promising efficacy data demonstrated in the Phase 2b PARADIGM study.

NeuroSense has strategically bolstered its supply chain by implementing comprehensive Chemistry, Manufacturing, and Controls (CMC) enhancements that positions the company for a robust and expeditious commercial launch. The company has established a resilient manufacturing infrastructure supply chain by fully qualifying U.S. and Canadian Drug Master File (DMF) and Certificate of Suitability (CEP) holders for both of its Active Pharmaceutical Ingredients (APIs). These steps enable dependable and compliant sourcing for commercial-scale production volumes.

Additionally, the Company is pleased to report that it is partnering with a global Contract Development and Manufacturing Organization (CDMO) that currently manufactures PrimeC clinical batches and will also support its future commercial supply. All analytical methods supporting drug product release and stability have been fully validated, and the manufacturing process has been successfully scaled to commercial levels. Stability data support a shelf life of at least 36 months at room temperature, and formulation IP granted in 2023 provides protection through 2042.

"This manufacturing milestone represents a critical leap forward in our commercialization roadmap," said Alon Ben-Noon, CEO of NeuroSense. "With commercial-scale production validated and a 36-month room-temperature shelf life confirmed, PrimeC is now positioned to rapidly enter the Canadian market upon regulatory approval. This achievement, coupled with our patent protection through 2042, strengthens our ability to deliver PrimeC to ALS patients who urgently need new therapeutic options."

NeuroSense is actively working to advance discussions with Health Canada to pursue early market entry through the Notice of Compliance with Conditions (NOC/c) pathway, a regulatory mechanism designed to expedite access to promising therapies for serious conditions with significant unmet medical needs. While commercial forecasts suggest potential peak annual revenue of \$100–150 million in Canada, early market entry would not only address an urgent medical need but also provide valuable real-world data and a strategic foundation for global expansion and reinforce NeuroSense's long-term growth strategy and market position.

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 that target multiple pathological pathways associated with these diseases.

For additional information, we invite you to visit our [website](#) 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 a commercial launch in Canada and market potential. 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 commercial launch of PrimeC will not be expeditious, that there will not be dependable and compliant sourcing for commercial-scale production volumes of PrimeC, that the shelf life of PrimeC will not be as anticipated, lower than anticipated market

opportunity in Canada and elsewhere, that regulatory approvals for PrimeC will be delayed or not obtained in Canada or elsewhere; insufficient capital to complete development of PrimeC, the timing of expected regulatory and business milestones; 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; 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 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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For further information: For further information: Email: info@neurosense-tx.com, Tel: +972 (0)9 799 6183

Additional assets available online:  [Photos \(1\)](#)

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