NeuroSense Investor Relations

NeuroSense Advances PrimeC Toward New Drug Submission to Health Canada for ALS

The planned submission follows alignment with Health Canada on the NDS pathway and is supported by additional PARADIGM data, including a survival benefit and consistent effects across PrimeC's multi-pathway biomarker program

CAMBRIDGE, Mass., July 22, 2026 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (NASDAQ: NRSN) ("NeuroSense"), a late-stage clinical biotechnology company focused on developing disease-modifying treatments for neurodegenerative diseases, today announced it intends to proceed with the filing of a New Drug Submission (NDS) to Health Canada (the "Agency") for PrimeC for the treatment of amyotrophic lateral sclerosis (ALS), following a constructive Pre-New Drug Submission ("Pre-NDS") meeting with the Agency. NeuroSense expects to complete and file the submission in the coming months.

The recent Pre-NDS meeting was held following the generation of substantial additional evidence from the Phase 2b PARADIGM clinical program. NeuroSense presented Health Canada with a comprehensive update to its proposed NDS package, including achievement of the study's prespecified primary TDP-43 biomarker endpoint (p=0.0421), long-term survival (14.9-month median survival benefit, HR 0.35 and p=0.0037), external natural history analyses, and additional mechanistic and translational data generated since the Company's initial regulatory interaction. The meeting also included an expert clinical perspective from a leading Canadian ALS specialist, as well as additional supportive analyses that will form part of the planned NDS package, further strengthening the growing body of evidence supporting PrimeC's potential in ALS.

"This marks an important milestone in our regulatory strategy for PrimeC," said Alon Ben-Noon, Chief Executive Officer of NeuroSense. "The additional evidence generated through the PARADIGM program - from achievement of the primary TDP-43 biomarker endpoint to the meaningful long-term survival outcome - has significantly strengthened our planned submission package and reinforces our confidence in PrimeC's potential to address the substantial unmet need faced by people living with ALS. We appreciate Health Canada's constructive engagement throughout the Pre-NDS process and look forward to completing our submission."

NeuroSense plans to continue to work with Health Canada as it prepares the NDS filing, and looks forward to providing further updates as the submission advances.

About NeuroSense

NeuroSense Therapeutics is a late-clinical stage biotechnology company developing novel treatments for severe neurodegenerative diseases, including amyotrophic lateral sclerosis (ALS) and Alzheimer's disease. The Company's lead product candidate, PrimeC, is a novel oral therapy designed to target multiple key biological pathways underlying disease progression, including neuroinflammation, oxidative stress and dysregulated iron metabolism.

NeuroSense has recently completed analysis of long-term follow-up data from its Phase 2b PARADIGM study in ALS, supporting meaningful slowing of disease progression. The Company also reported significant biological activity across multiple biomarkers associated with ALS, including microRNAs, supporting PrimeC's multi-target mechanism of action. and representing a potentially important advance in the treatment of ALS.

NeuroSense has received clearance from the U.S. Food and Drug Administration (FDA) to initiate a pivotal Phase 3 clinical trial (PARAGON) in ALS, which is expected to enroll approximately 300 participants, primarily in the United States.

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.

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

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.

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 including statements regarding regulatory plans and the timing thereof in Canada and the future development of PrimceC. 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 potential of PrimeC. 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 potential NDS submission will be delayed or not occur; the uncertainty regarding outcomes and the timing of current and future clinical trials; the risk that PrimeC will not advance towards later-stage development, timing for reporting data, including from the study of PrimeC in Alzheimer's disease; that the study will not be successful; 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 March 31, 2026 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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