

NeuroSense Therapeutics Granted Key Patent for its ALS Drug PrimeC in Australia

- Patent valid through 2038
- Phase 2b ALS trial expected to commence H1 2022

CAMBRIDGE, Mass., March 1, 2022 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (Nasdaq: NRSN) ("NeuroSense"), a company developing treatments for severe neurodegenerative diseases, today announced the grant of a key patent in Australia. The patent, which was already granted in the US in 2021 (US 10,980,780), is titled "Methods and compositions of anti-inflammatory drug and dicer activator for treatment of neuronal diseases", and covers the Company's unique fixed-dose combination of ciprofloxacin and celecoxib, two US FDA-approved drugs that are the active ingredients in PrimeC, NeuroSense's lead development candidate for treating Amyotrophic Lateral Sclerosis ("ALS"). This patent will last until June 2038, subject to appropriate maintenance and renewal.

"The additional coverage for our key patent further confirms the novelty of our approach of combining two drugs to act in synergy to improve the way that ALS is treated," stated Alon Ben-Noon, NeuroSense's CEO. "Along with the granting of Orphan Drug Designation in both the US and Europe, this patent grant strengthens our commercialization strategy and brings us closer to addressing the needs of ALS patients worldwide."

Similar patent applications are pending in the European Patent Office, Japan, Canada, and Israel. Additional patent applications relating to the novel formulation of PrimeC and methods for the treatment of other neurodegenerative diseases using NeuroSense's platform combination therapy are pending as well.

As previously [disclosed](#), NeuroSense plans to initiate its ALS Phase 2b study in May 2022. The double-blind, placebo-controlled, multicenter study will enroll patients in Israel and the US to evaluate the final formulation of PrimeC.

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 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, NeuroSense's strategy is to develop combined therapies targeting multiple pathways associated with these diseases.

NeuroSense completed a Phase 2a clinical study with 15 ALS patients in 2021. In this study, PrimeC was given in an intermediate formulation for 12 months to all of the patients. The study results showed meaningful clinical outcomes along with ALS related biological markers that were significantly changed, indicating a biological activity of PrimeC. NeuroSense plans to initiate a Phase 2b study, double-blind, placebo controlled, multicentered in Israel and the US in the first half of 2022 to evaluate the final formulation of PrimeC. PrimeC is a novel extended-release formulation composed of unique doses of two FDA-approved drugs, which aim to synergistically inhibit the progression of ALS. PrimeC has received orphan drug status from the FDA and EMA.

In addition, NeuroSense has recently announced the third stage of its collaboration with Massachusetts General Hospital in Boston on novel Neuron-Derived Exosomes (NDEs) to determine further the biological changes in ALS related pathologies and the effect of PrimeC on the relevant targets.

NeuroSense is also advancing programs in Alzheimer's disease and Parkinson's disease, and is aiming to initiate clinical studies in these indications in the first half of 2023.

For additional information we invite you to visit our [website](#) 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. 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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