NeuroSense Investor Relations

NeuroSense Therapeutics to Present at Upcoming U.S. and European ALS Conferences

- ***Biomarker data to be presented provide indication of PrimeC's efficacy in ALS***
- ***Phase IIb PARADIGM ALS trial's primary endpoints include biomarkers and ALS-related hallmarks***
- ***Topline results expected H1 2023***

CAMBRIDGE, Mass., Sept. 21, 2022 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (Nasdaq: NRSN) ("NeuroSense"), a company developing treatments for severe neurodegenerative diseases, today announced scientific presentations at two upcoming conferences.

Europe: TRICALS Consortium 2022 Masterclass

Dr. Shiran Zimri, Head of Scientific Program at NeuroSense and Dr. Ferenc Tracik, the Company's Chief Medical Officer, will be presenting at the TRICALS Consortium 2022 Masterclass that joins leading amyotrophic lateral sclerosis (ALS) experts, European patient advocacy groups, and ALS foundations, on September 28th-30th, 2022 in the Netherlands. NeuroSense will present on the use of biomarkers in ALS clinical studies.

TRICALS is the largest European research initiative to find a cure for ALS to date with 48 top research centers in 16 countries which joined hands with patient organizations and fundraisers to reach one goal: find effective treatments for ALS.

U.S.: ALS ONE's 5th Annual ALS Research Symposium

Dr. Tracik will present NeuroSense's latest clinical updates and findings in his talk titled "Shifting the Paradigm-PrimeC: A Potential Disease-Modifying Treatment for ALS Driven by Novel Biomarkers Measuring Mechanism of Action" at ALS ONE's 5th Annual ALS Research Symposium, to be held virtually on October 6th-7th and 11th, 2022. This marks the third year NeuroSense will present at ALS ONE's symposium.

With a focus on the Company's Phase IIb PARADIGM PrimeC study, Dr. Tracik will present the latest findings on ALS-related biomarkers identified by NeuroSense. PARADIGM is now enrolling patients in Israel and plans to commence enrollment in Europe and the U.S. in the next several weeks.

ALS ONE's 5th Annual ALS Research Symposium unites researchers, clinicians, and individuals living with ALS from around the world for three days of sharing important ALS research and hope. Hosted by the ALS ONE research team: Dr. Robert Brown, MD, DPhil, of UMass Memorial Medical School; Dr's Merit Cudkowicz, MD, MSc, James Berry, MD, MPH, and Sabrina Paganoni, MD, PhD, of the Sean M Healey & AMG Center for ALS at Massachusetts General Hospital; and Dr. Fernando Vieira, MD, of The ALS Therapy Development Institute.

"We believe NeuroSense's highly innovative approach of using biomarkers as a primary efficacy endpoint in our Phase IIb PARADIGM study, combined with our pioneering work in identifying ALS-related biomarkers, improves the likelihood of better patient outcomes," said Dr. Tracik. "As a combination drug, PrimeC is designed to target multiple pertinent mechanisms in this complex disease, and through biomarkers, we are able to closely track our drug's impact and efficacy."

About PARADIGM

NeuroSense's Phase IIb PARADIGM trial is currently enrolling patients to assess PrimeC's efficacy, as well as safety and tolerability, in people living with ALS. The study is randomizing 69 people living with ALS in a 2:1 ratio to receive PrimeC or placebo, respectively. Primary endpoints of the study include assessment of ALS biomarkers, evaluation of clinical efficacy, improvement in quality of life, as well as safety and tolerability.

About PrimeC

PrimeC, NeuroSense's lead drug candidate, a combination therapy for ALS, was granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). NeuroSense completed a Phase IIa clinical study which successfully 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's upgraded formulation, which is a unique extended-release tablet, developed to maximize the synergism between the compounds, is now being evaluated in a Phase IIb clinical trial, PARADIGM, for the treatment of 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 patients are diagnosed with ALS in the U.S. alone, with an annual disease burden of $1 billion. The number of patients with ALS is expected to grow 24% by 2040 in the U.S. and EU.

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 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 the company's participation in scientific conferences; 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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For further information: For further information: Email: info@neurosense-tx.com, Tel: +972 (0)9 799 6183

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