NeuroSense Investor Relations

NeuroSense Announces Peer-Reviewed Publication of PrimeC Phase IIa ALS Study in Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration

- *Groundbreaking ALS biomarker research: Marks the first publication of NeuroSense's novel biomarker results demonstrating PrimeC's effect on ALS related hallmarks*
- *PrimeC showed a statistically significant impact on key disease-related biomarkers including TDP-43, which increases with disease progression, and LC3, a key autophagy marker*
- *Based on successful Phase IIa results, NeuroSense commenced PARADIGM, a Phase IIb clinical trial in May 2022*

CAMBRIDGE, Mass., Sept. 19, 2022 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (Nasdaq: NRSN) ("NeuroSense"), a company developing treatments for severe neurodegenerative diseases, today announced the peer-reviewed publication of Phase IIa clinical data in *Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration* in a paper titled, "Combination of ciprofloxacin/celecoxib as a novel therapeutic strategy for ALS" authored by NeuroSense's Head of Scientific Program, Dr. Shiran Zimri, and Head of ALS Program, Avital Pushett, along with leading amyotrophic lateral sclerosis (ALS) researchers. View the paper in full here: LINK

Data in the paper are results from NeuroSense's Phase IIa study of its lead drug candidate, PrimeC, a unique and proprietary combination of two FDA-approved drugs—ciprofloxacin and celecoxib—in the treatment of ALS.

Key data from the paper include:

Safety:

- The study met its primary endpoint of safety in a 12-month clinical trial with 15 participants living with ALS.

Efficacy and Biomarkers:

- Exploratory efficacy was evaluated by ALSFRS-R and FVC, and blood samples were taken before and during the study for biomarker analysis.
- PrimeC showed statistically significant changes in ALS-related biomarkers of serum neuron-derived exosomes (NDEs) such as TDP-43 and LC3 as measured by ExoSORT™ indicating a positive biological activity.
- The trial was open-label, comparing the data generated to the PROACT database utilizing propensity matching.

Conclusions:

- This study supports the safety and tolerability of PrimeC in ALS.
- Biomarker analyses suggest early evidence of a biological effect.

"This clinical study is a very important achievement and milestone for the ALS community. It is very encouraging to see that there was both biological activity and clinical signals of a treatment effect," said Vivian Drory, MD, Director of the Neuromuscular Diseases Unit at Tel Aviv Sourasky Medical Center and Principal Investigator of the study. "I am thankful to all participants, their families, and staff who took part in this study, and proud and excited to participate in the PARADIGM study, which utilizes an upgraded formulation of PrimeC."

Based on the results of this study, NeuroSense commenced PARADIGM, a Phase IIb clinical trial in May 2022. PARADIGM is randomizing 69 people living with ALS at 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.

"This study, as well as previously published preclinical work, provides strong encouragement for the continued development of Prime C. We need more treatments for ALS, and PrimeC is an exciting candidate," stated Jeremy M. Shefner, MD, PhD, FAAN, Professor of Neurology, Chief Medical Officer for Clinical Research, at Barrow Neurological Institute, and co-author of the paper.

Dr. Erez Eitan, co-author of the study and Chief Scientific Officer of NeuroDex, stated, "We are proud to work with NeuroSense's team on the implementation of ExoSORT™, our proprietary method for isolating neuron-derived exosomes from blood samples for identification and measurement of biomarkers. When we discovered that TDP43, a major ALS biomarker, and LC3, an autophagy biomarker, can be measured in NDEs and are different in ALS patients, we hoped this would help to advance therapeutic development. We are thankful to

NeuroSense for providing us with the opportunity to test the biomarkers in their clinical trials." NeuroDex is advancing brain diagnostics through its proprietary cell-specific exosome diagnostic platform providing a noninvasive, inexpensive, and robust diagnostic tool.

"We thank the trial participants along with their families and caregivers for choosing to participate in this study. We would also like to thank all of our invaluable collaborators for their teamwork and relentless effort in the field and in this study," stated NeuroSense's Head of Scientific Program, Dr. Shiran Zimri.

"We are very pleased to have our Phase IIa findings of PrimeC published in a leading ALS journal, as interest in PrimeC continues to grow in the ALS scientific community. Our clinical research and scientific teams are actively presenting at conferences as we engage with patient advocacy groups with the aim of bringing a much needed effective treatment to people suffering from this debilitating disease," stated NeuroSense CEO Alon Ben-Noon.

About PrimeC

PrimeC, NeuroSense's lead drug candidate is a combination therapy that 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. 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. Through a collaboration with Massachusetts General Hospital in Boston on novel Neuron-Derived Exosomes (NDEs), NeuroSense is working to further determine the biological changes in ALS-related pathologies and the effect of PrimeC on relevant targets.

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 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.

Photo - https://mma.prnewswire.com/media/1901692/NeuroSense_1.jpg
Photo - https://mma.prnewswire.com/media/1901693/NeuroSense_2.jpg

SOURCE NeuroSense Therapeutics

For further information: For further information: Email: info@neurosense-tx.com, Tel: +972 (0)9 799 6183

Additional assets available online: Photos (2)

https://neurosense.investorroom.com/2022-09-19-NeuroSense-Announces-Peer-Reviewed-Publication-of-PrimeC-Phase-IIa-ALS-Study-in-Amyotrophic-Lateral-Sclerosis-and-Frontotemporal-Degeneration