NeuroSense Investor Relations

NeuroSense Announces Positive PrimeC Pharmacokinetic Study Results & Anticipates Phase IIb ALS Enrollment to Expand into the US

Pharmacokineticic (PK) profile of PrimeC supports the formulation's extended release properties, as the active components are released simultaneously

CAMBRIDGE, Mass., Sept. 28, 2022 /PRNewswire/ -- NeuroSense Therapeutics Ltd. (Nasdaq: NRSN) ("NeuroSense"), a company developing treatments for severe neurodegenerative diseases, today announced results from its multi-dose PK study (NCT05436678) of its lead drug candidate PrimeC for the treatment of amyotrophic lateral sclerosis (ALS). It is expected that these PK data, combined with the current Phase IIb PARADIGM study, will assist NeuroSense in designing a pivotal Phase III trial of PrimeC for the treatment of ALS in alignment with U.S. Food and Drug Administration (FDA) requirements.

PrimeC is a proprietary combination therapy and unique extended release formulation of two FDA approved drugs, celecoxib and ciprofloxacin.

"With this additional multi-dose PK study, we have achieved another important milestone in our PrimeC ALS development plan. The results confirm the favorable safety and improved PK profile of PrimeC in this unique formulation," stated NeuroSense's Chief Medical Officer, Dr. Ferenc Tracik.

The randomized, multiple-dose, two-treatment, two-period crossover study compared PrimeC to its reference products, co-administered celecoxib and ciprofloxacin, under an FDA-cleared IND. In each period of the study, either two PrimeC tablets or co-administered ciprofloxacin and celecoxib were administered to 20 subjects every 12 hours for 6.5 days (13 total administrations) in fed conditions.

The results of the study demonstrate that PrimeC's unique formulation resulted in a simultaneous release of ciprofloxacin and celecoxib under fed conditions, as compared to co-administration of the reference products. In addition, the attained PK profile and bioavailability of PrimeC under steady state conditions (with drug concentrations consistently remaining within therapeutic limits for an extended period) further support the PrimeC dosing regimen used in the current PARADIGM trial.

The data further demonstrated a clear safety profile for PrimeC under steady state conditions, as a comparison of PrimeC to ciprofloxacin and celecoxib shows that the C_{max}, AUC_{0-t}, and $AUC_{0-\infty}$ are lower for both components of PrimeC compared to the highest approved doses of each of the components administered separately. Moreover, these findings indicate it would be appropriate to rely on safety data available for each of the approved reference drugs, ciprofloxacin and celecoxib, in a 505(b)(2) application pathway.

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, designed to maximize the synergism between the compounds, is now being evaluated in a Phase IIb clinical trial, PARADIGM, for the treatment of ALS.

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. Topline data are expected mid-2023.

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.

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