

## European Medicines Agency Grants NeuroSense SME Status

- **SME status offers regulatory guidance and engagement in dialogue with EMA**
- **NeuroSense to open an EU office in Ulm, Germany**
- **Company plans to enroll patients at multiple sites across Europe in its planned Phase 3 pivotal ALS study of PrimeC**

CAMBRIDGE, Mass., Sept. 20, 2023 /PRNewswire/ -- [NeuroSense Therapeutics Ltd.](#) (NASDAQ: NRSN) ("NeuroSense"), a company developing treatments for severe neurodegenerative diseases, announced today that it has opened an EU Office as well as been granted the Small and Medium-Sized Enterprise (SME) status by the European Medicines Agency (EMA), which offers significant benefits leading up to and following drug regulatory approval. The EMA already granted PrimeC Orphan Drug Status for the treatment of ALS.

NeuroSense completed enrollment in PARADIGM, its Phase 2b multinational clinical study of PrimeC for the treatment of ALS. One-third of the 69 enrolled patients came from sites located in Europe. Clinical topline results from PARADIGM are expected at the end of 2023.

The Company expects to commence a global pivotal Phase 3 study of PrimeC in ALS in 2024 with a vast number of clinical sites in Europe. As Europe is a key market, in addition to the USA, NeuroSense has opened an office in Ulm, Germany to lead its regulatory dialogue with the EMA and clinical operations during the planned Phase 3 study.

SME status offers benefits, including regulatory guidance and engagement in early dialogue with a multidisciplinary EMA team throughout the development program. In addition, financial benefits such as a 100% fee reduction for scientific advice and inspections of facilities for orphan products, as well as a fee exemption following marketing authorization of PrimeC in its first year of sales.

"SME status with the EMA comes at an opportune time for NeuroSense as we look ahead to clinical topline Phase 2b results with the expectation that it will lead us rapidly into a pivotal Phase 3 study for ALS," stated NeuroSense Founder and CEO, Alon Ben Noon. "We plan to work closely with the EMA on the PrimeC development strategy towards the initiation of the Phase 3 study across Europe and appreciate their support of our mission in ALS."

### 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 timing of clinical top-line results of, and the results of, the PARADIGM clinical trial and the timing of a pivotal Phase 3 study for ALS and a pivotal Phase 3 study for PrimeC. Further, forward-looking statements are subject to a number of risks and uncertainties as a result of which actual results could differ materially and adversely from those anticipated or implied in the forward looking statements. These risks include a delay in the reporting of clinical top-line results from PARADIGM clinical trial and a delay in patient enrollment for a pivotal ALS study of PrimeC; greater than anticipated costs and expenses; the potential for PrimeC to safely and effectively target ALS; preclinical and clinical data for PrimeC; the timing of current and future clinical trials, timing for reporting data; the nature, strategy and focus of the company and further updates with respect thereto; the development and commercial potential of any product candidates of the company; and other risks and uncertainties set forth in NeuroSense's filings with the Securities and Exchange Commission (SEC), including NeuroSense's Annual Report on Form 20-F filed with the*

*SEC on March 22, 2023. 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.*

Logo: [https://mma.prnewswire.com/media/1707291/NeuroSense\\_Therapeutics\\_Logo.jpg](https://mma.prnewswire.com/media/1707291/NeuroSense_Therapeutics_Logo.jpg)

SOURCE NeuroSense

For further information: For further information: Email: [info@neurosense-tx.com](mailto:info@neurosense-tx.com), Tel: +972 (0)9 799 6183/ Nigel Sillitoe, [sillitoe@insight-discovery.com](mailto:sillitoe@insight-discovery.com), +971 (0) 55 880 9676

---

Additional assets available online: [Photos \(1\)](#)

<https://neurosense.investorroom.com/2023-09-20-European-Medicines-Agency-Grants-NeuroSense-SME-Status>