

PRESS RELEASE 8 September 2025

Recipharm partners with NeuroSense Therapeutics to advance ALS therapy PrimeC toward Phase 3 trials

- Recipharm showcases advanced formulation expertise in complex fixed-dose development
- Overcame significant physicochemical and pharmacokinetic challenges to enable controlled release
- Supporting late-stage clinical and commercial supply for NeuroSense's ALS therapy PrimeC.

Recipharm, a leading global contract development and manufacturing organisation (CDMO), has partnered with NeuroSense Therapeutics (Nasdaq: NRSN) to develop PrimeC, an advanced fixed-dose combination tablet designed to target multiple disease mechanisms in Amyotrophic Lateral Sclerosis (ALS).

PrimeC is NeuroSense's patented, proprietary novel therapy for ALS that combines two drugs already approved by the FDA for other indications, working synergistically to slow disease progression by addressing key pathological processes such as microRNA dysregulation, iron accumulation and neuroinflammation.

Recipharm's scientists addressed significant formulation challenges posed by combining two active ingredients with very different physicochemical and pharmacokinetic properties. Together with NeuroSense, they developed a unique, controlled-release tablet that synchronises the release of both active ingredients to achieve the desired therapeutic profile. Advanced formulation strategies were also applied to ensure stability, taste-masking and scalability for late-stage clinical trials and future commercial supply.

Greg Behar, Recipharm's CEO said: "We are proud to contribute to the development of a therapy with the potential to make a meaningful difference for people living with ALS. Developing PrimeC required overcoming significant formulation challenges, and I am proud of our team's ability to create a robust, scalable solution. This collaboration reflects Recipharm's strength in tackling complex therapies and advancing innovative treatments for patients with rare and devastating diseases like ALS."

Alon Ben-Noon, NeuroSense's CEO said: "Recipharm's formulation expertise has been instrumental in advancing PrimeC toward late-stage clinical development. We are excited to move forward with Phase 3 trial and commercialisation readiness in order to bring this important therapy closer to patients."

ALS is a rare, progressive neurodegenerative disorder that affects voluntary muscle control, leading to the gradual loss of the ability to speak, move and breathe. Despite medical advances, treatment options remain limited, and most patients succumb to the disease within three to five years of diagnosis.

Following successful preclinical studies and a multinational Phase 2b clinical trial demonstrating promising results, NeuroSense is preparing for a pivotal Phase 3 study in 2025. In parallel, the company is also advancing plans to provide early access to PrimeC for people living with ALS in Canada through Health Canada's NOC/c regulatory pathway. Recipharm will support the



manufacturing registration and commercial batches for the Canadian market in the second half of 2025.

PrimeC has already been granted Orphan Drug Designation by both the US FDA (Food and Drug Administration) and the EMA (European Medicines Agency), underscoring its potential to address an urgent unmet medical need.

As a trusted partner for complex drug development, Recipharm combines deep scientific expertise, advanced manufacturing capabilities and a commitment to quality to accelerate the path from laboratory innovation to patient access.

For more information on Recipharm's drug development capabilities, please contact Uwe Hanenberg, <u>Uwe.Hanenberg@Recipharm.com</u>

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For more information

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 people are diagnosed with ALS in the U.S. alone, with an annual disease burden of \$1 billion. The number of people living with ALS is expected to grow by 24% by 2040 in the U.S. and EU.

About PrimeC

PrimeC, NeuroSense's lead drug candidate, is a novel extended-release oral formulation composed of a unique fixed-dose combination of two FDA-approved drugs: ciprofloxacin and celecoxib. PrimeC is designed to synergistically target several key mechanisms of ALS that contribute to motor neuron degeneration, inflammation, iron accumulation and impaired ribonucleic acid ("RNA") regulation to potentially inhibit the progression of ALS. NeuroSense completed a Phase 2a clinical trial which 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 was granted Orphan Drug Designation by the U.S. Food and Drug Administration and the European Medicines Agency.

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 <u>website</u> and follow us on <u>LinkedIn</u>, <u>YouTube</u> and \underline{X} . Information that may be important to investors may be routinely posted on our website and these social media channels.

About Recipharm

Recipharm is a leading Contract Development and Manufacturing Organisation (CDMO) employing over 5,000 employees worldwide. Recipharm provides manufacturing services of pharmaceuticals in various dosage forms, including sterile fill & finish, oral solid dosage and biologics; clinical trial material development and manufacturing services; and pharmaceutical product development. Its Advanced Bio division works with customers to develop and commercialise advanced therapy medicinal products (ATMPs): pre-clinical to clinical development, commercial development and manufacture for new biological modalities, encompassing technologies based on live viruses and



viral vectors, live-microbial biopharmaceutical products, nucleic acid-based mRNA and plasmid DNA production.

Recipharm manufactures several hundred different products to customers ranging from big pharma to smaller research and development companies. It operates development and manufacturing facilities in France, Germany, India, Israel, Italy, Portugal, Spain, Sweden and the US.

For more information on Recipharm, please visit www.recipharm.com and www.recibiopharm.com

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