

SNT-4728 completes recruitment in Phase 2 sleep disorder trial supported by Parkinson's UK

- **Final patient recruited into Syntara's randomised, double-blind, placebo-controlled Phase 2 study of first-in-class neuro-targeted anti-inflammatory therapy, SNT-4728, to treat isolated REM Sleep Behaviour Disorder (iRBD).**
- **iRBD affects around 2% of individuals over 50 years of age, and up to 90% of these patients progress to a neurodegenerative disease, highlighting a substantial unmet medical need.**
- **In addition to assessing safety, the study is evaluating the ability of SNT-4728 to reduce inflammation in brain regions linked to the progression of various neurodegenerative disorders, including Parkinson's disease.**
- **The study is being conducted in collaboration with leading academic centres and is supported by Parkinson's UK through its Parkinson's Virtual Biotech program in partnership with the Parkinson's Foundation**
- **Top-line results are expected in Q2 CY26, making this one of five Syntara clinical studies with data readouts anticipated during calendar year 2026.**

Syntara Limited (ASX: SNT), a clinical-stage drug development company, is pleased to announce that the final patient has been enrolled into its randomised, double-blind, placebo-controlled Phase 2 clinical trial of SNT-4728 in patients with isolated REM Sleep Behaviour Disorder (iRBD), a severe sleep disorder associated with a high risk of progression to neurodegenerative disease. With recruitment now complete and patients undergoing a three-month treatment period, top-line results are expected in Q2 CY26.

iRBD is estimated to affect approximately 2% of people over 50 years of age, and the multi-centre study is evaluating Syntara's first-in-class neuro-targeted anti-inflammatory therapy in this population. Long-term observational studies suggest that up to 90% of individuals with iRBD subsequently develop a neurodegenerative disease such as Parkinson's disease or Dementia with Lewy bodies, positioning iRBD as the strongest clinical predictor of these disorders.

The study is designed to evaluate the potential impact of SNT-4728 across two important and complementary dimensions:

- The study includes advanced brain imaging at baseline and after the 12-week treatment period to determine whether SNT-4728 reduces neuroinflammation in key brain regions implicated in the progression from iRBD to Parkinson's disease and related neurodegenerative disorders
- The study contains an exploratory secondary endpoint to assess whether treatment with SNT-4728 improves the clinical symptoms of iRBD.

Evidence of reduced neuroinflammation on brain imaging would support the broader hypothesis that SNT-4728 has the potential to modify disease biology during the prodromal phase of neurodegeneration. In turn, such findings would represent a meaningful advance in the field and are likely to be of strong interest to Syntara's existing funding partners, Parkinson's UK, as well as other philanthropic organisations and pharmaceutical companies.

"A positive outcome from this study could potentially change the field," said Professor Simon Lewis, Director of the Parkinson's Disease Research Clinic at Macquarie University. "For patients with iRBD, demonstrating an improvement in symptoms would offer immediate hope in a condition where treatment options are currently very limited. At the same time, evidence that SNT-4728 reduces neuroinflammation in key brain regions would provide important insight into whether intervening at this early (prodromal) stage could influence the processes that lead to Parkinson's disease and related disorders."

Syntara Chief Executive Officer Gary Phillips said on the completion of recruitment: *"This has been a complex and logistically challenging study, and I would like to sincerely thank the principal investigators, Prof Simon Lewis and Prof Michele Hu, the study staff and, most importantly, the patients who have participated. Their commitment has made it possible to conduct a trial that addresses fundamental questions about both symptom relief and disease biology in iRBD."*

I would also like to take this opportunity to express my thanks to Prof Andrew Scott and his team in Melbourne for conducting nationwide PET imaging for the Australian component of the study. Their unwavering support and dedication made it possible for us to commence the study within a meaningful timeframe."

This trial sits within our broad portfolio of clinical programs, from which we are expecting five data read outs through the course of 2026. Together, these studies have the potential to meaningfully advance our pipeline and inform future development and partnering opportunities."

The Phase 2 iRBD study is being conducted in collaboration with leading academic centres and is supported by Parkinson's UK through its Parkinson's Virtual Biotech program in partnership with the Parkinson's Foundation, underscoring the strategic importance of targeting neuroinflammation in the earliest stages of neurodegenerative disease.

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About Syntara

Syntara Limited (ABN: 75 082 811 630) is a clinical stage drug development company targeting extracellular matrix dysfunction with its world-leading expertise in amine oxidase chemistry and other technologies to develop novel medicines for blood cancers and conditions linked to inflammation and fibrosis.

Lead candidate amsulostat (also known as SNT-5505 and previously as PXS-5505) is for the bone marrow cancer myelofibrosis which causes a build-up of scar tissue that leads to loss of red and white blood cells and platelets. Amsulostat has been granted Fast Track Designation, having already achieved FDA Orphan Drug Designation and clearance under an Investigational New Drug Application for development in myelofibrosis. Amsulostat has now completed a Phase 2a trial in myelofibrosis in which it was dosed as monotherapy and in combination with a JAK inhibitor. Two Phase 1c/2 studies with amsulostat in patients with a blood cancer called myelodysplastic syndrome has been initiated.

Syntara is also advancing topical pan-LOX inhibitors with SNT-9465 in a Phase 1a/b study of hypertrophic scars and continuing the ongoing collaboration with Professor Fiona Wood and the University of Western Australia studying SNT-6302 in keloid scars. SNT-4728 is being studied in collaboration with Parkinson's UK as a best-in-class SSAO/MAO-B inhibitor to treat sleep disorders and slow progression of neurodegenerative diseases like Parkinson's by reducing neuroinflammation.

Other Syntara drug candidates target fibrotic and inflammatory diseases such as kidney fibrosis, MASH, pulmonary fibrosis and cardiac fibrosis.

Syntara developed two respiratory products available in world markets (Bronchitol® for cystic fibrosis and Aridol®- a lung function test), which it sold in October 2023.

Syntara is listed on the Australian Securities Exchange, code SNT. The company's management and scientific discovery team are based in Sydney, Australia. www.syntaraTX.com.au.

Forward-Looking Statements

Forward-looking statements in this media release include statements regarding our expectations, beliefs, hopes, goals, intentions, initiatives or strategies, including statements regarding the potential of products and drug candidates. All forward-looking statements included in this media release are based upon information available to us as of the date hereof. Actual results, performance or achievements could be significantly different from those expressed in, or implied by, these forward-looking statements. These forward-looking statements are not guarantees or predictions of future results, levels of performance, and involve known and unknown risks, uncertainties and other factors, many of which are beyond our control, and which may cause actual results to differ materially from those expressed in the statements contained in this document. For example, despite our efforts there is no certainty that we will be successful in partnering any of the products in our pipeline on commercially acceptable terms, in a timely fashion or at all. Except as required by law we undertake no obligation to update these forward-looking statements as a result of new information, future events or otherwise.

SOURCE:

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