## Media Release

08 August 2024

# New indication for Syntara lead asset SNT-5505 as German MDS study group awarded A$2.5m grant to conduct phase 2 blood cancer trial

- **Researchers at Heidelberg University to take SNT-5505 into the clinic for the blood cancers myelodysplastic syndrome (MDS) and chronic myelomonocytic leukemia (CMML) with A$2.5m funding from Deutsche Krebshilfe (German Cancer Aid)**
- **The phase 1b/2 study (AZALOX) in patients with high risk MDS and CMML will commence Q1 2025, running in parallel with the previously announced Australian phase 1c/2 study in low/intermediate risk MDS patients**
- **7 German specialist centres have agreed to join the study, which has been prioritised by the German MDS Study Group. The grant will cover the cost of the study and Syntara will provide SNT-5505.**
- **The Phase 2 trials in myelofibrosis and MDS give SNT-5505 a combined blood cancer market opportunity of approximately US$6b**

Clinical stage drug development company Syntara Limited (ASX: SNT) is pleased to announce that University Medical Center Mannheim (UMM) at Heidelberg University in Germany will lead a Phase 1b/2 clinical trial investigating the efficacy of Syntara's lead asset, SNT-5505, in high-risk MDS patients.

The clinical study follows a long-term pre-clinical research collaboration between Syntara and Medical Faculty Mannheim at Heidelberg University. Under the guidance of Professor Wolf-Karsten Hofmann and Professor Daniel Nowak, the collaboration resulted in a Nature Communications publication[1] in 2023 that demonstrated a doubling of response rate to standard therapy when combined with pan-LOX inhibitor SNT-5505.

The AZALOX study in patients with high-risk MDS and CMML will commence in Q1 2025, complementing the previously announced Australian Phase 1c/2 study in low/intermediate risk MDS patients, set to begin in Q4 2024. Seven specialist centres in Germany have already agreed to participate in the study, which has been prioritised by the German MDS Study Group.

The Phase 2 trials in myelofibrosis and MDS present a combined market opportunity for Syntara and its lead SNT-5505 asset of approximately US$6 billion.

The AZALOX study will begin with a dose-escalation phase where two doses of SNT-5505 will be administered to a maximum of 12 patients over six months, in combination with the hypomethylating drug 5-azacytidine (5-AZA). This will be followed by an expansion phase, where 30 patients will receive the selected dose of SNT-5505 and 5-AZA for six months.

Professor Wolf-Karsten Hofmann , Director of the III Medical Clinic, Chair of the Cancer Center at UMM and head of the AZALOX study said: “We hope that the rapid transfer of this outstanding scientific work directly into the treatment of MDS patients will enable patients with this severe hematopoietic disorder to be able to do without blood transfusions in the future. Additionally, we see a good chance that this will reduce the risk of a transformation of myelodysplastic neoplasia into acute myeloid leukemia"

Syntara CEO Gary Phillips, said: "We are eager to further explore the potential of SNT-5505 in addressing significant unmet needs in the treatment of MDS. The interest amongst academic clinical researchers is a direct response and validation of our long-term collaboration with Heidelberg University. By expanding our clinical trials to include both high-risk and low/intermediate risk MDS patients, we are positioning SNT-5505 as a potential treatment option for all MDS patients. This indication adds both clinical and commercial value to SNT-5505 where our ongoing myelofibrosis study is already fully recruited and will report interim data later this year."

MDS comprises a group of blood cancers with clinical and pathological features similar to acute myeloid leukemia (AML). These conditions are most common in older adults, with an annual incidence of up to 75 cases per 100,000. The current standard of care for high-risk MDS includes treatment with hypomethylating agents (HMAs) like 5-AZA and decitabine. Although approximately 50% of MDS patients initially respond to HMAs, subsequent relapse is common, highlighting the urgent need for new compounds that enhance the efficacy of existing treatments.

Heidelberg University has received a German Cancer Aid grant of A$2.5m to cover the costs of the study and Syntara will provide trial supplies of SNT-5505.

1. Inhibition of lysyl oxidases synergizes with 5-azacytidine to restore erythropoiesis in myelodysplastic and myeloid malignancies; Nature Communications 2023; https://doi.org/10.1038/s41467-023-37175-8

#ENDS#

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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.

Syntara is managing three phase 2 clinical studies in diseases of high unmet need with a further two potential phase 1c/2 studies being evaluated for 2024. Lead candidate SNT-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. SNT-5505 has already achieved FDA Orphan Drug Designation and clearance under an Investigational New Drug Application for development in myelofibrosis. After encouraging phase 2a trial results when used as a monotherapy in myelofibrosis, SNT-5505 is now being studied with a JAK inhibitor in a further phase 2 myelofibrosis study with interim data by Q4 2024. Protocols for another two phase 1c/2 studies with SNT-5505 in patients with a blood cancer called myelodysplastic syndrome are in development and expected to commence recruitment by Q1 2025.

Syntara is also advancing both oral and topical pan-LOX inhibitors in scar prevention and scar modification programs as part of an ongoing collaboration with Professor Fiona Wood and the University of Western Australia. SNT-4728 is being studied in collaboration with Parkinson's UK as a best-in-class SSAO/MAOB 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, NASH, 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 2024.

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.