

Syntara to add new blood cancer indication to SNT-5505 clinical development plan following Australian government grant for phase 2 study

- **Phase 2 trial evaluating combination treatment of SNT-5505 with chemotherapy in patients with low and intermediate risk myelodysplastic syndrome (MDS) to commence later this year.**
- **University of Newcastle and its partners Syntara and the Australasian Leukaemia and Lymphoma Group (ALLG) awarded \$0.83m in a competitive grant process by the Australian Medical Research Future Fund (MRFF).**
- **SNT-5505 combination therapy has potential to reduce transfusion dependence and improve quality of life for MDS patients in a US\$3.5b per annum global market, a significant additional blood cancer indication to add to the ongoing development in myelofibrosis (MF).**

Clinical stage drug development company Syntara Ltd (ASX: **SNT**) has announced a new Phase 2 trial evaluating combination treatment of SNT-5505 with chemotherapy in patients with low and intermediate risk MDS. The trial, to commence later this year, will be led by Associate Professor Anoop Enjeti at Australia's University of Newcastle, and will be conducted under the clinical trial framework of the Australasian Leukaemia and Lymphoma Group (ALLG), the leading investigator run national blood cancer trials network with more than 160 trials undertaken.

This trial will feature a dose escalation phase where up to 9 MDS patients who are transfusion dependent will be treated with a fixed dose of SNT-5505 and two different doses of a hypomethylating agent followed by a dose expansion phase where 30 patients will be treated for 6 months on the dose combination selected in the first phase based on tolerability and efficacy. Endpoints will include the reduction in transfusion dependency, haematological parameters and quality of life. Results from the dose escalation phase including safety and preliminary efficacy endpoints are anticipated by mid-2025.

Blood cancers are on the rise and now represent the second most common cause of cancer-related deaths in Australia. Myelodysplastic syndromes are a significant subset of these blood cancers where abnormal tissue growth leads to bone marrow failure, often featuring low blood counts leading to infections, transfusion dependence and risk of

progression to acute myeloid leukemia (AML), a more aggressive form of blood cancer. Overall 5-year survival rate for transfusion dependent MDS is only 37%.

Dr. Enjeti, Senior Staff Specialist Haematologist/Conjoint Associate Professor University of Newcastle said, "Transfusion dependent myelodysplasia has no approved treatments available for Australian patients. It is exciting that that MRFF funding will facilitate the collaboration between multiple partners translating the pre-clinical synergies between SNT-5505 and hypomethylating agents, into an early phase clinical trial with potential for improving the survival and quality of life for our patients."

Delaine Smith, ALLG Chief Executive Officer said, "The ALLG is the only collaborative blood cancer clinical trial group in Australasia, conducting clinical trials into MDS, AML and other leukaemias, lymphomas and myeloma. We are excited to launch this partnership to bring an important new treatment arm to the MDS05 MYDAS-T – MESSAGE trial and advance research opportunities for Australian patients with MDS."

Gary Phillips, Syntara Chief Executive Officer commented, "The grant from the MRFF and the support of University of Newcastle and the ALLG enables us to expand the haematology indications for SNT-5505 beyond the current international myelofibrosis study and into another area of high unmet need and commercial value. The possibility of seeing safety and efficacy data in this additional indication in the same time frame as the other phase 2 studies in MF, neurodegenerative disease and burn scars is a win for the company and its shareholders and will generate significant interest in SNT-5505 amongst companies with a focus on haematology."

SNT-5505 (previously called PXS-5505) is Syntara's lead asset, a pan-LOX inhibitor which is being evaluated in a Phase 2 multinational study targeting MF. Data from the first phase of this study where the drug was used on its own was accepted for an oral presentation at the American Society of Haematology (ASH) in San Diego last December where it was presented at the New Therapeutic Frontiers session. The first patient in the follow-on study where SNT-5505 is being dosed in combination with the JAK inhibitor ruxolitinib in myelofibrosis patients was recruited last December. The study is on track to be fully recruited by mid-2024 with the first preliminary data ready for presentation at the December 2024 ASH conference.

Syntara's contribution to the MDS study is \$700k over the three years the dose escalation and expansion phases are expected to run, as well as supplying the study drug and LOX assays on tissue samples taken during the study.

#ENDS#

SOURCE:

Syntara Limited (ASX: SNT),
Sydney, Australia
(ABN: 75 082 811 630)

AUTHORISED FOR RELEASE TO ASX BY:

Syntara Limited Disclosure Committee.
Contact: David McGarvey, Chief Financial
Officer, and Company Secretary:

+61 2 9454 7200,
david.mcgarvey@syntaraTX.com.au

CONTACT:

Syntara Media:

Felicity Moffatt:
+61 418 677 701
felicity.moffatt@syntaraTX.com.au

Syntara Investor relations:

Rudi Michelson
(Monsoon Communications)
+61 411 402 737
rudim@monsoon.com.au

JOIN THE SYNTARA MAILING LIST [HERE](#)



About Syntara

Syntara Limited (ABN: 75 082 811 630) is a clinical stage drug development company with a focus on blood-related cancers. The company's highly productive drug discovery engine is driven by its expertise in amine oxidase inhibitors.

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.

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), for which it receives royalties.

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.

About ALLG

The Australasian Leukaemia and Lymphoma Group (ALLG) is Australia's and New Zealand's only collaborative clinical trial organisation that sponsors local investigator-initiated clinical trials. Established 50 years ago in 1973, the ALLG's membership of over 1,300 blood cancer health professionals includes haematologists, clinician researchers, scientists and nurses treating leukaemia, lymphoma, myeloma, myelodysplastic syndromes and other haematological malignancies. The ALLG plans, designs, conducts, monitors and publishes investigator initiated clinical trials to create better treatments and better lives for patients with blood cancers.

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.