

Phase 2 blood cancer trial fully recruited – interim results due December 2024

- **Recruitment target achieved as 15th patient dosed**
- **12 patients exceed one month treatment and surpasses minimum threshold proposed in FDA discussions for safety evaluation.**
- **No drug related dropouts & no serious adverse reactions**
- **Syntara expects to announce interim data in December 2024, spurring additional regulatory discussions**

Clinical stage drug development company Syntara Limited (ASX: SNT) is pleased to announce that it has completed full recruitment in its Phase 2 trial evaluating SNT-5055, in combination with ruxolitinib, treating the bone marrow cancer myelofibrosis.

After commencement of the open-label study in December 2023, Syntara has reached the milestone with the 15th patient dosed yesterday and has already exceeded the minimum threshold of one month treatment for 12 patients proposed in FDA discussions for safety evaluation.

The trial is being conducted across 19 clinical trial sites in the USA, Australia, South Korea and Taiwan. SNT-5505 is a pan-LOX inhibitor and the lead asset in Syntara's proprietary clinical pipeline.

Syntara expects to report interim results from the trial in late 2024, in conjunction with the American Society of Hematology (ASH) Annual Meeting. In line with the excellent safety profile observed in earlier phase 1 and phase 2 studies, no drug related dropouts nor any serious adverse reactions have been observed to date.

The reassuring safety profile, alongside the interim data, is expected to allow Syntara to engage with and discuss pivotal study design with the FDA in Q1 2025, with the full 12-month data set to be available in Q3 2025.

Syntara CEO Gary Phillips said: "I'd like to thank the haematology clinics, investigators and the Syntara clinical team for achieving this significant milestone in such a timely fashion. We now look forward to presenting our interim data later in the year and building a solid foundation for the next stage of discussions with the FDA and potential strategic partners."

Syntara commenced the combination trial after it found encouraging efficacy and an excellent safety profile in a Phase 2 monotherapy trial of the drug, as presented at ASH in December 2023. An effective pan-LOX inhibitor, such as SNT-5505, for myelofibrosis has disease modifying potential for patients and would unlock a market conservatively estimated to be more than \$1 billion per annum.

SNT-5505 is a pan-LOX inhibitor that has also demonstrated compelling pre-clinical data when used in combination with standard of care in other haematological malignancies such as myelodysplastic syndrome and solid tumours like those found in hepatocellular carcinoma and pancreatic cancer.

#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 8760 1480,
david.mcgarvey@syntaraTX.com.au

CONTACT:

Syntara investor / media relations:

Matthew Wright
NWR Communications
+61 451 896 420
matt@nwrcommunications.com.au

JOIN THE SYNTARA MAILING LIST [HERE](#)





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. The protocol for another phase 1c/2 study with SNT-5505 in patients with a blood cancer called myelodysplastic syndrome is in development and expected to commence recruitment in 2H 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), 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.