Media Release

10 June 2025

SNT-5505 awarded US FDA Fast Track designation

Highlights:

- **US FDA Fast Track designation granted for Syntara's SNT-5505 for the treatment of myelofibrosis**
- **Fast Track designation enables more frequent FDA interaction, eligibility for Priority Review and discussions on accelerated approval**
- **Reflects significant unmet medical need in myelofibrosis, a serious blood cancer with limited treatment options**

Sydney, Australia – 10 June 2025: Syntara Limited (ASX: SNT), a clinical-stage biotechnology company focused on developing first-in-class treatments in blood cancers and other fibrotic diseases, today announces that its lead candidate, SNT-5505, has been granted Fast Track designation by the US Food and Drug Administration (FDA) for the treatment of myelofibrosis in patients with an inadequate response to JAK inhibitor therapy.

Fast Track designation can be awarded by the FDA after its review of data demonstrating potential benefit, a mechanistic rationale for efficacy and early clinical evidence. With the published and peer reviewed pre-clinical and clinical data, as well as presentations at preeminent hematology meetings, there is a growing body of evidence supporting SNT-5505.

Fast Track designation aims to expedite the review and development of therapies that address serious conditions and unmet medical needs, facilitating earlier drug approval and patient access. Benefits include:

- More frequent meetings and communication with the FDA.
- Eligibility for Accelerated Approval and Priority Review, subject to meeting relevant criteria.
- Potential for Rolling Review in support of a New Drug Application (NDA).

Myelofibrosis is a rare and serious type of bone marrow cancer affecting approximately 15 per 1 million people worldwide, with about 20,000 patients in the US alone. Current standard of care, primarily JAK inhibitors, are often associated with significant side effects leading to high discontinuation rates.

SNT-5505 represents a novel therapeutic approach by inhibiting lysyl oxidases, key enzymes in fibrosis and growth factor signalling pathways. Clinical studies to date have demonstrated SNT-5505's ability to significantly enhance patient

quality of life by improving symptom scores together with an excellent safety and tolerability profile.

Gary Phillips, Chief Executive Officer of Syntara, stated:

"To have the FDA recognise the quality of the pre-clinical and clinical results generated to date, as well as the therapeutic promise of SNT-5505 through this Fast Track designation, is an outstanding development for Syntara. This supports our efforts to rapidly advance SNT-5505 as a potential new standard of care for patients with myelofibrosis, addressing the noticeable gaps left by existing treatments."

Syntara continues to advance SNT-5505 through its Phase 2 clinical trial, with additional interim data to be presented at the European Hematology Association meeting on Saturday 14 June 2025 (Sunday 15 June AEST).

#ENDS#

SOURCE:
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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 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 suboptimal response setting. 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 H1 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/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.