Media Release

11 August 2025

Syntara receives guidance from FDA on next stages of amsulostat clinical progression

Syntara Limited (ASX: SNT), a clinical-stage drug development company, today announces that it has received feedback from the US Food and Drug Administration (FDA) regarding the next stages of clinical development for amsulostat in myelofibrosis (MF).

During a Type C meeting, the FDA reviewed a comprehensive data package that included interim data (as presented at the European Hematology Association congress in June 2025) from the ongoing open label trial (MF-101) of amsulostat in combination with ruxolitinib, as well as a proposal for a pivotal registrational study.

The FDA has provided guidance that a Phase 2 trial with a control arm be undertaken to acquire additional safety and efficacy data, focussing on improvements in symptoms and spleen volume reductions in order to optimise the design and efficiency of a subsequent pivotal Phase 3 trial.

Syntara CEO Gary Phillips said: *"Over the coming period we will use the FDA guidance to refine our clinical development plan for amsulostat and continue discussions with partners based on the FDA recommended path forward.*

Syntara is in a strong position given the depth and quality of our pipeline and a cash runway that will take us into 2027. We look forward to sharing results from our ongoing clinical trials over the coming months."

Syntara's updated clinical pipeline development plan is shown in the following table:

Drug Candidate	Indication	Phase	Anticipated Upcoming Milestones	Addressable market (US$ billion)
Amsulostat	Myelofibrosis	Phase 1c/2	Top line 12-month data Q3 2025	**~$1b**
	Myelodysplastic Syndrome Low & Intermediate Risk + High Risk trials	Phase 1c/2	Interim Data H1 2026	**~$3.2b**
SNT-9465	Hypertrophic Scars	Phase 1a/b	Data H1 2026	**~$3.5b**
SNT-6302	Keloid Scars	Phase 1c	Data H2 2026	**~$3.5b**
SNT-4728	IRBD and Parkinson's Disease	Phase 2	Data H1 2026	**~$3.5b**

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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 recently been granted Fast Track Designation, having 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, amsulostat is now being studied with a JAK inhibitor in a suboptimal response setting. A Phase 1c/2 study with amsulostat in patients with a blood cancer called myelodysplastic syndrome has been initiated, with a second trial planned to commence recruitment in Q3, 2025.

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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