

## Amsulostat poised for late-stage clinical development following positive FDA feedback

- **Positive Type C meeting outcome with US FDA supporting the Phase 2b design for Syntara's lead asset amsulostat**
- **Amsulostat on target to advance into late-stage clinical development with a ~100 patient, placebo-controlled Phase 2b study in myelofibrosis**
- **Competitive and differentiated drug profile with near term potential for indication extension as two additional phase 1b/2 trials in myelodysplastic syndrome (MDS) report interim data in 2H 2026**
- **Agreed clinical development pathway enhances amsulostat's profile and supports engagement with potential commercial partners**
- **Syntara to deliver further near-term catalysts in CY2026 including top-line data from its Phase 2 iRBD/Parkinson's trial, two sets of results from its Phase 1b skin scarring studies**

**Syntara Limited (ASX: SNT)**, a clinical-stage drug development company, is pleased to announce that it has received positive feedback from the U.S. Food and Drug Administration (FDA) following a constructive in person Type C meeting regarding the planned Phase 2b clinical trial of its lead candidate, amsulostat, for the treatment of patients with myelofibrosis (MF) who have had an inadequate response to standard of care.

Following a review of amsulostat's development to date, the FDA supported the proposed Phase 2b study design and provided guidance on the detail of the study and overall development pathway for amsulostat. This feedback represents a major milestone for the company, enabling progression into late-stage clinical development and creating opportunity for further engagement with potential commercial partners.

The Phase 2b study will be a double blind, placebo-controlled study of amsulostat added to standard of care (JAK inhibition) for patients who have had an inadequate response. The primary endpoint will be achievement of 50% reduction in total symptom score (TSS50) after 9 months of treatment. Subject to final protocol review, the number of patients to be studied is expected to be approximately 100.

Syntara Chief Executive Officer Gary Phillips said: *"We are delighted to have received a positive FDA review of the trial protocol for the planned Phase 2b study. Amsulostat has a differentiated and competitive safety and efficacy profile, with strong potential as a breakthrough therapy for MF patients with an inadequate response to standard of care. We are also advancing amsulostat's development into myelodysplastic syndrome (MDS), where two clinical studies are currently ongoing.*

*With additional clinical milestones expected over the next 12 months, including top-line data from the Phase 2 study of SNT-4728 for isolated REM sleep behaviour disorder (iRBD), a prodromal feature of Parkinson's disease, and results from a placebo-controlled study of SNT-9465, a topical pan-LOX inhibitor for hypertrophic scarring; 2026 is shaping up to be a landmark year for Syntara."*

#ENDS#

### **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 been granted Fast Track Designation, having already achieved FDA Orphan Drug Designation and clearance under an Investigational New Drug Application for development in myelofibrosis. Amsulostat has now completed a Phase 2a trial in myelofibrosis in which it was dosed as monotherapy and in combination with a JAK inhibitor. Two Phase 1c/2 studies with amsulostat in patients with a blood cancer called myelodysplastic syndrome have been initiated.

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](http://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

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