

New positive interim data in Phase 2 study of SNT-5505 in myelofibrosis

Syntara Limited (ASX:SNT), a clinical-stage drug development company, is pleased to announce further positive interim data from its ongoing Phase 2 clinical trial evaluating SNT-5505 (200 mg BID) in combination with ruxolitinib (RUX) for the treatment of myelofibrosis (MF). This data will be presented at the European Hematology Association (EHA) Conference on Sunday 15 June 2025 AEST, and builds upon the positive interim results announced at the American Society of Hematology (ASH) Annual Meeting in December 2024.

The latest interim results further highlight the safety and clinical benefits of SNT-5505's unique mechanism of action and competitive profile in treating MF patients who have had a suboptimal response to existing standard of care.

Patients in the trial had been treated with ruxolitinib (RUX) for an average of three years with symptom scores, spleen sizes and blood counts indicative of high disease burden.

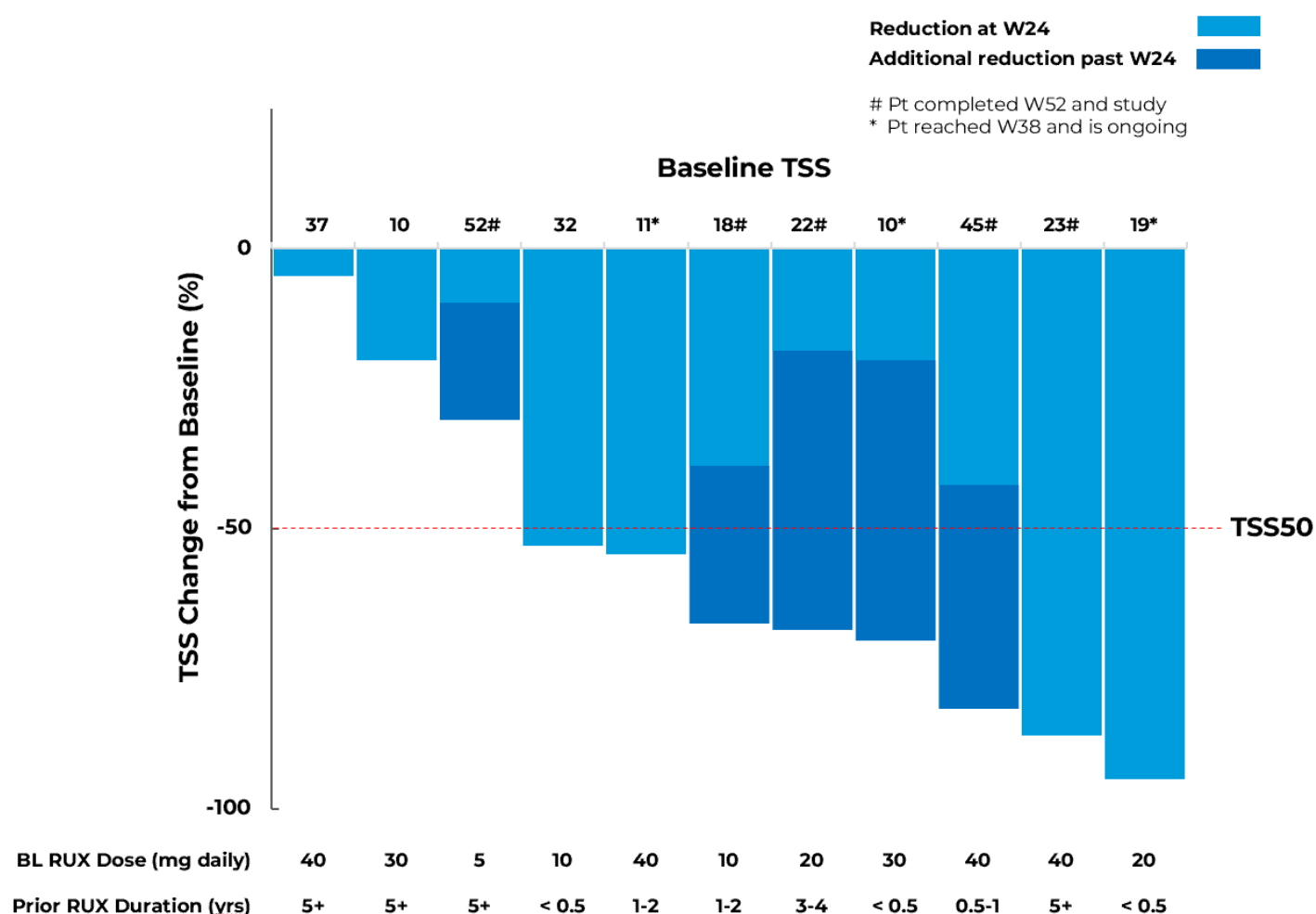
Highlights:

- 73% (8/11) of evaluable¹ patients achieved TSS50² at 24 weeks of treatment or beyond.
- 44% (4/9) of evaluable³ patients achieved a spleen volume reduction (SVR) of 25%⁴ at Week 24 or beyond. Notably there were no increases in dosage of concomitant RUX that might otherwise explain the impact of SNT-5505 on spleen volume.
- The continued improvement in patient symptoms and spleen volume is a novel finding that differentiates SNT-5505 from MF drugs on market and in later stages of development. It highlights the potential of SNT-5505 to be used in combination with JAK inhibitors to change the long-term outcomes for MF patients.
- SNT-5505 is safe and well tolerated, with no treatment related serious adverse events (SAEs) attributed to SNT-5505; providing additional and important differentiation to MF drugs on market and in development.
- Syntara to engage with the FDA in Q3 on study results and trial design for a pivotal Phase 2c/3 study.

The open-label study, which aims to assess the safety and efficacy of SNT-5505 over 52 weeks, enrolled 16 patients with intermediate-2 or high-risk MF. 11 patients reached 24 weeks of treatment, the normal duration of most MF studies, 8 patients reached 38 weeks of treatment and 5 of those patients have completed the full 52 weeks of treatment with the remaining 3 scheduled to complete in Q3 2025 after which the final study results will be reported. The patient withdrawal rate is consistent with that seen in other MF studies of patients with similar disease severity.

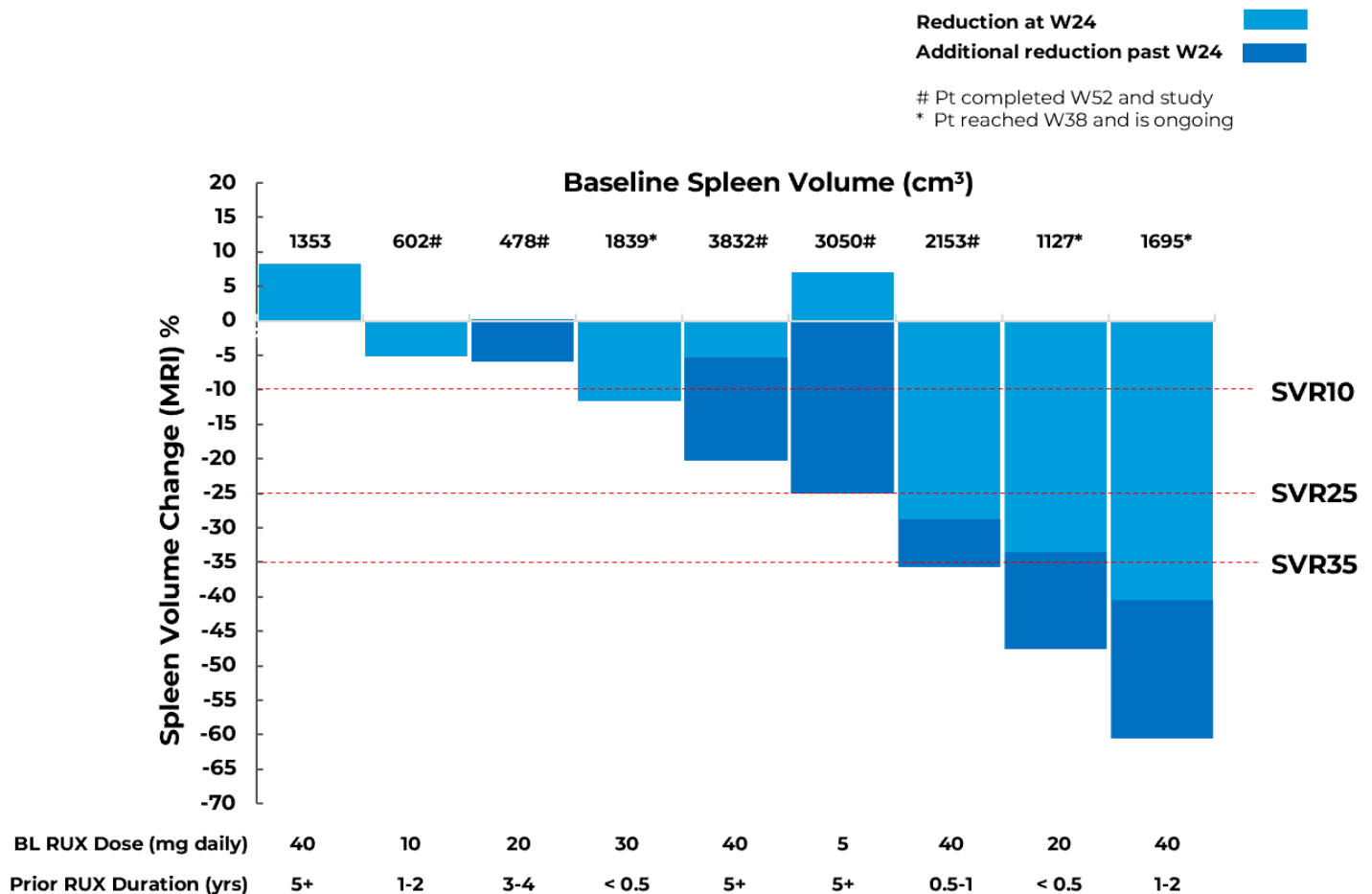
Key points from the latest interim data:

- **Good safety and tolerability:**
 - SNT-5505, in combination with a stable dose of RUX, was safe and well tolerated with no treatment related serious adverse events (SAEs) attributed to SNT-5505.
- **Symptom relief continues for patients:**
 - 73% (8/11) evaluable patients achieved TSS50 at Week 24 or beyond.
 - Mean TSS reduction from baseline to Week 38 (n=8) was -56%.
 - Mean TSS reduction from baseline to Week 52 (n=5) was -63%.



- **Improved Spleen Volume Reduction (SVR):**

- At Week 24, 7/9 (78%) evaluable patients experienced stable or reduced spleen volume with no increases in RUX dose.
- 4/9 (44%) evaluable patients achieved SVR25 at Week 24 or beyond.



- **Hematology:**

- Hemoglobin levels and platelet counts were generally stable across the cohort.
- One (of 2) transfusion-dependent patients showed reduced transfusion requirements (at least 50% reduction from baseline) over the period of the interim data (Minor response⁵).
- One (of 7) transfusion independent patient had 10 g/L increase in Hb (Minor response⁵).

[The full EHA presentation is available here.](#)

Next Steps

The remaining 3 patients in the study are scheduled to complete 12 months of treatment in Q3 2025, after which the final study results will be reported.

Syntara will engage in discussion with the FDA in Q3 regarding the study results and trial design for a pivotal Phase 2c/3 study. Concurrently, the company will continue to engage in discussions with potential global and regional partners.

Syntara CEO Gary Phillips commented:

"After very recently being awarded Fast Track designation, the positive interim data to be presented at EHA 2025 further reinforces the promising profile of SNT-5505 as an add-on therapy for myelofibrosis patients with a suboptimal response to existing standard of care. The sustained and increasing improvements in both symptom burden and spleen volume, coupled with its excellent safety and tolerability, continue to differentiate SNT-5505 from other drugs in this space. We are particularly encouraged by the durability of the responses observed and look forward to reporting final study results and engaging with the FDA and potential partners in the coming months."

WEBINAR

Syntara's CEO Gary Phillips will discuss the latest data update as part of a webinar, which is being held at 11am AEST today, Friday 13 June 2025.

Shareholders, investors and interested parties are encouraged to register to attend the presentation at the following link:

https://us02web.zoom.us/webinar/register/WN_wpsVWntTQ72KldtsL4ntvg

After registering, you will receive a confirmation email containing information about joining the webinar as well as dial-in details for those that wish to join by phone.

Questions can be submitted live during the webinar or sent in advance to matt@nwrcommunications.com.au

Please note **a replay of the webinar will be available at the above-mentioned link** shortly following the conclusion of the live session.

FOOTNOTES

1. Evaluable patient for TSS defined as having TSS at baseline and week 24
2. TSS50 is ≥50% reduction in Myelofibrosis Symptom Assessment Form Total Symptom Score, the standard primary endpoint in MF clinical trials
3. Evaluable patient for SVR defined as SV > 450 cm³ at baseline, treated with RUX for ≥ 80% of time to week 24 and with week 24 assessment
4. SVR25 is a standard efficacy endpoint used in MF clinical trials for patients who are not well controlled on RUX
5. 2024 proposed IWG-ELN criteria

#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 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, 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.

About the Phase 2 Study:

The open-label study aims to evaluate the safety and efficacy of PXS-5505 (SNT-5505) over 52 weeks. It has enrolled patients with intermediate-2 or high-risk MF. Patients must have been on RUX for 12 weeks or more (stable background dose for 8 weeks or more) and be symptomatic (10 or more on the MFSAF v4.0). The study is being conducted across sites in Australia, South Korea, Taiwan, and the USA. As of the data cut-off, 13 patients reached 12 weeks, 11 patients reached 24 weeks, 8 patients reached 38 weeks, and 5 patients reached 52 weeks (completed).

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.