

Skin scarring program to progress on positive Phase 1a results

- **Next generation topical anti-fibrotic, SNT-9465, to progress to Phase 1b study in hypertrophic scars following successful completion of Phase 1a**
- **Phase 1a Single Ascending Dose clinical trial confirmed dose-dependent target engagement with good safety profile**
- **Randomised, double-blinded, placebo-controlled innovative Phase 1b trial design for hypertrophic scars using state of the art evaluation tools to commence ahead of schedule**
- **Fiona Wood Foundation / University of Western Australia exploratory clinical trial in keloid scarring using first generation Syntara topical drug reaches 50% recruitment**
- **Syntara's portfolio and clinical trial program on track to deliver multiple outcomes in 2026.**
- **KOL webinar to be held with Professor Ardeshir Bayat at 11am AEDT today. [Register here.](#)**

Syntara Limited (ASX:SNT), a clinical-stage drug development company, is pleased to announce that its next-generation topical pan-lysyl oxidase (pan-LOX) inhibitor SNT-9465, has successfully completed a first-in-human Phase 1a study and is poised to progress in an innovative Phase 1b study in participants with hypertrophic scars.

The Phase 1a dose escalation study in 32 healthy volunteers evaluated creams containing a placebo and 4 different doses of SNT-9465 to determine the optimal dose for complete lysyl oxidase inhibition. The results announced today confirm dose-dependent target inhibition and an acceptable tolerability safety profile, paving the way for progression to an integrated Phase 1b study in hypertrophic scars.

The Phase 1b study is a randomised, double-blinded, placebo-controlled split-scar trial in 20 adult participants with hypertrophic sternotomy scars. The study will enrol patients with scars that are 3-12 months in age, a minimum of 15 cm in length and a width of 1-2 cm. Each participant will treat themselves for three months with both the blinded active treatment and placebo to distinct portions of their scar with a 5 cm buffer in between. At the end of the treatment period the scar regions will be assessed by a number of state-of-the-art evaluation tools.

This initiative builds on the success and findings of the SOLARIA2 trial which used an earlier generation compound, SNT-6302, to demonstrate the therapeutic

potential of topical pan-LOX inhibition by reducing scar tissue collagen content, increasing vascularisation and promoting beneficial structural changes within scar tissue.¹

Globally renowned skin scarring scientist and surgeon Professor Ardeshir Bayat², said: *"Skin scarring represents one of the largest untreated burdens in medicine, despite its profound physical, functional and psychosocial impact. For the first time, we now have the clinical tools and molecular insight to meaningfully intervene. The biological rationale for topical pan-lysyl oxidase inhibition has always been compelling, and the robust target engagement demonstrated in the Phase 1a study reinforces SNT-9465 as a uniquely promising therapeutic candidate. I'm encouraged by the progress to date and look forward to the next stage of clinical development."*

Results are expected in 2026 and will support an FDA Investigational New Drug (IND) application, paving the way for a global development program targeting the first approved pharmacological treatment for skin scarring.

Syntara CEO Gary Phillips said: *"The learnings from the earlier SOLARIA2 study have been incorporated into this Phase 1b study to enable us to truly evaluate the commercial attractiveness of topical pan-LOX inhibition in a multi-billion dollar market. Current standard of care, which includes costly laser therapy or painful steroid injections, requires multiple treatments to produce small incremental improvements. A daily topical treatment with SNT-9465 has the potential to provide profound patient benefits that can be effective without the need for repeat clinical visits."*

Alongside the study of SNT-9465 and hypertrophic scars, the parallel scarring program under the leadership of Professor Fiona Wood is focused on keloid scars, which differ biologically from hypertrophic scars and present unique challenges for patients. Recruitment for the Syntara-supported pilot study, SATELLITE, has progressed well, with 50% of the subjects having commenced treatment, and the study remains on track to deliver results in 2026.

Webinar

Syntara is pleased to advise that it is hosting a webinar with Professor Bayat, joined by Syntara CEO Gary Phillips, Head of Drug Discovery Dr. Wolfgang Jarolimek and Chief Medical Officer Dr. Jana Baskar.

The webinar will discuss:

- Current landscape for the treatment of skin scarring, including the unmet medical need (Professor Bayat)
- Update on SNT-9465, covering the history of the project, current status of the clinical program and commercial potential for the drug (Syntara)

WEBINAR DETAILS

11:00 am AEDT – Wednesday 26 November 2025

[Click here to register](#)

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. <https://www.science.org/doi/10.1126/scitranslmed.adv2471>.
2. Director Medical Research Council of South Africa Wound Healing Unit, University of Cape Town

#ENDS#

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Trial Design	
Name of trial	An Integrated Phase 1a/1b, First-in-human, Randomized, Double-blinded, Placebo-controlled Split-scar Study in a Cohort of Adult Participants with Hypertrophic Sternotomy Scars to Evaluate Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics
Trial number	ACTRN12625001285448
Primary objective	To investigate the safety and tolerability of single ascending doses and multiple doses of SNT-9465 in healthy volunteers and participants with hypertrophic sternotomy scars.
Secondary objectives	<ul style="list-style-type: none"> To investigate the pharmacokinetics (PK) of SNT 9465 when administered as single ascending doses and multiple doses; To investigate the pharmacodynamics (PD) of SNT-9465 when administered as single ascending doses and multiple doses; To obtain preliminary measures of scar changes associated with administration of multiple doses of SNT-9465 in participants with hypertrophic sternotomy scars; To define the recommended Phase 2 dose (RP2D) and schedule of SNT-9465.
Blinding status	Blinded
Placebo controlled	Yes
Trial design	<p>Part A: Single topical doses of SNT-9465 evaluated at ascending concentrations across 4 cohorts. Sentinel dosing pattern will be followed for all cohorts. Within each cohort, 8 subjects will be randomly assigned to one of the two groups (SNT-9465 or placebo) in a 3:1 ratio respectively wherein each subject will receive a single dose of the active drug or placebo.</p> <p>Part B: Repeat once daily topical dosing of SNT-9465 and placebo in 20 adult participants with hypertrophic sternotomy scars over 90 days.</p>
Treatment route	Topical
Treatment frequency	Once daily
Number of subjects	<p>Part A: 24 on active treatment and 8 on placebo</p> <p>Part B: 20 on active treatment and placebo (intra-participant)</p>
Subject selection criteria	<p>Part A: Healthy participants between 18 and 60 years</p> <p>Part B: Male or female aged between 18 and 70 years (inclusive) at the screening visit. Diagnosed with hypertrophic sternotomy scars, with all of the following characteristics:</p> <ol style="list-style-type: none"> Total scar length ≥ 15 cm; width 1-2 cm, ensuring 2×7 cm² segments with 3-5 cm buffer; Height ≥ 2 mm; Do not extend beyond the general geographic margins of the wound; Present for a minimum of 3 months and no longer than 12 months after surgery at commencement of dosing.
Trial locations	WA and QLD
Commercial partners involved	No commercial partner

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.

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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