Media Release

15 July 2025

First patient dosed in SATELLITE Phase 1c clinical trial for keloid scars

Highlights:

- First patient dosed in Phase 1c SATELLITE study evaluating topical lysyl oxidase inhibitor SNT-6302
- Investigator-Initiated Trial (IIT) led by renowned burns and wound specialist, Professor Fiona Wood, in partnership with the University of Western Australia (UWA)
- Study aims to assess safety, tolerability, and preliminary efficacy of multiple applications of SNT-6302 in active keloid scars
- Addressing unmet clinical need in global keloid and hypertrophic scar market, exceeding US$3.5 billion annually
- Phase 1 trial of next-generation agent, SNT-9465, in hypertrophic scars expected to commence by the end of July

Syntara Limited (ASX: SNT), a clinical-stage drug development company, is pleased to announce that the first patient has been dosed in the SATELLITE study — a Phase 1c clinical trial investigating the safety and tolerability of its topical lysyl oxidase inhibitor SNT-6302 (formerly known as PXS-6302) for the treatment of keloid scars.

The SATELLITE trial, led by Professor Fiona Wood and conducted through the Fiona Wood Foundation and UWA, addresses the critical unmet need for effective treatments in keloid scarring. Keloid scars grow over time in area and depth, are disfiguring and debilitating and often associated with chronic pain, itch, and significant psychological distress. Current treatment options are limited and only partially effective, highlighting the need for novel therapeutic approaches.

"Keloid scars present unique challenges distinct from other forms of scarring, including hypertrophic scars," said Professor Fiona Wood, principal investigator of the trial. "The SATELLITE study aims to explore whether multiple topical applications of SNT-6302 can significantly improve patient outcomes, not only by reducing the volume of the scar but also alleviating associated symptoms such as pain and itch."

The trial follows promising results from the SOLARIA2 study, where a three-month treatment with SNT-6302 demonstrated a 30% reduction in collagen content and improved vascularisation in established scars — processes considered pivotal in addressing keloid pathology.

The SATELLITE trial is an open-label study with a placebo-controlled component for patients presenting with multiple keloids. Up to 20 participants, aged 18 years and above, with active keloids measuring between 5 and 25 cm^2 will undergo a 4-week placebo run-in period. Subsequently, participants will apply topical SNT-6302 four days per week for a treatment period of three months. Safety, tolerability, pharmacokinetics, and preliminary efficacy — including changes in keloid volume, collagen attenuation, tissue stiffness, and patient-reported outcomes of pain and itch — will be rigorously assessed.

At this time, Professor Wood and Gary Phillips, CEO of Syntara, would like to take the opportunity to acknowledge the enormous contribution made over more than a decade by Dr Mark Fear, who sadly passed away in an accident on the morning of 4 July 2025. Mark was a Senior Scientist at the Fiona Wood Foundation and an Associate Professor at UWA's Burn Injury Research Unit.

Fiona Wood said: "Mark pushed the boundaries of knowledge over many years' specifically with the aim to solve the problem of fibrosis. He instilled in the team the need to challenge dogma backed up with clarity in experimental design in exploring the problems faced. He will be sorely missed but his legacy will build into the future."

Gary Phillips added: "Mark inspired and encouraged us from the very beginning to explore pharmacological skin scarring treatments and has been fundamental to our understanding of the science behind it. We aim to honour his legacy as we continue to address the significant clinical issues in the management of scars, leveraging our expertise alongside world-class research partners, to provide much-needed therapeutic alternatives for patients globally."

Syntara plans to dose the first patient with its next-generation topical pan-LOX inhibitor, SNT-9465, in a Phase 1 study targeting hypertrophic scars, by the end of July. Ethics approval has been secured, and preparatory site initiation activities have been successfully completed.

#ENDS#

SOURCE:
Syntara Limited (ASX: SNT),
Sydney, Australia
(ABN: 75 082 811 630)

AUTHORISED FOR RELEASE TO ASX BY:
Syntara Limited Disclosure Committee.

CONTACT:

Syntara investor / media relations:
Matthew Wright
NWR Communications
+61 451 896 420
matt@nwrcommunications.com.au

JOIN THE SYNTARA MAILING LIST HERE

Trial Design	
Name of trial	A Phase 1c Study Investigating the **SA**fety and **T**ol**E**rability of a **L**ysy**L** Oxidase **I**nhibi**T**or (PXS-6302) in the am**E**lioration of Keloids (The SATELLITE study)
Trial number	ACTRN12625000269437
Primary objective	• To investigate the safety and tolerability of multiple applications of PXS-6302 in treating active keloids over a period of 3 months • To investigate the change in keloid volume • To investigate changes in reported symptoms of pain and itch
Secondary objectives	• To investigate the pharmacokinetics of PXS-6302 with multiple applications of a single dose • To investigate the changes in keloid collagen attenuation, vascularisation, and tissue stiffness after 3 months of PXS-6302 treatment
Blinding status	Open-label (double-blind for participants with multiple keloids)
Placebo controlled	Yes, for participants with multiple keloids
Trial design	The study will consist of a screening period, placebo run-in period, treatment period and follow-up period. Those participants that meet the eligibility criteria will be admitted to the study site and given the placebo cream to apply four days per week during the 4-week placebo run-in period. Following application of treatment on Day 1, participants will be required to apply topical PXS-6302 in their home setting for a total period of 3 months. In participants that have multiple keloids, one keloid will be treated with PXS-6302 and a second keloid will be treated with placebo to provide their own control. In these cases, the treatment will be double-blinded. Participants will return to site at the following time-points; 4 weeks, 8 weeks and 3 months (end of treatment). Safety, tolerability, pharmacokinetic (PK) and efficacy assessments will be performed according to the study schedule.
Treatment route	Topical
Treatment frequency	Four days per week
Dose level	4 mg (2%) PXS-6302
Number of subjects	Up to 20 participants
Key Subject selection criteria	• Male or female and aged over 18 years at the screening visit • Active keloid greater than or equal to 5cm^2 and less than or equal to 25cm^2 in area that has persisted for a minimum of 4 weeks
Trial locations	Western Australia
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 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. Protocols for another two phase 1c/2 studies with amsulostat 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.