Media Release

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AZALOX MDS study advances to final Phase 1b dose cohort

- Phase 1b AZALOX study advances following completion of the first cohort evaluating amsulostat in combination with 5-Azacitidine in patients with high-risk myelodysplastic neoplasms & chronic myelomonocytic leukaemia
- No dose-limiting toxicities or new adverse events attributable to amsulostat were observed in the first cohort
- Drug Safety Monitoring Board approves dose escalation to final Phase 1b cohort, which will evaluate amsulostat at 200 mg twice daily
- All 10 German clinical sites initiated & open for recruitment
- Preliminary data from the study are expected Q4 CY26
- High-risk MDS represents a significant potential indication expansion & commercial opportunity for amsulostat beyond its FDA-supported development pathway in myelofibrosis

Syntara Limited (ASX: SNT), a clinical-stage drug development company, is pleased to announce completion of the first dose-escalation cohort in the Phase 1b component of the AZALOX clinical trial evaluating amsulostat, in combination with the hypomethylating agent 5-Azacitidine (5-AZA) in patients with high-risk Myelodysplastic Neoplasms (MDS) and Chronic Myelomonocytic Leukaemia (CMML).Following review of the safety data from the first cohort, the independent Drug Safety Monitoring Board (DSMB) has approved escalation to the final Phase 1b dose cohort, in which patients will receive amsulostat at 200 mg twice daily in combination with 5-AZA.The initial cohort evaluated amsulostat at 150 mg twice daily in combination with 5-AZA. No dose-limiting toxicities were observed and no new adverse events attributable to amsulostat were reported.

The Phase 1b component of AZALOX is intended to establish the safety profile and recommended Phase 2 dose of amsulostat in combination with 5-AZA. Subject to completion of the 200 mg cohort and review of the associated safety data, the study is expected to progress to a Phase 2 component designed to evaluate the safety and efficacy of the selected dose in approximately 30 patients.

Preliminary results from the completed Phase 1b dose-escalation component are expected during Q4 CY26.

All 10 participating clinical sites in Germany have now been initiated and are open for recruitment. Sites are actively pre-screened potential participants while awaiting the DSMB review, with patients already pre-registered for the 200 mg cohort.

Syntara Chief Executive Officer Gary Phillips said:

"Completion of the first AZALOX cohort without any dose-limiting toxicities and clearance to progress to the 200 mg dose represents an important step forward for the amsulostat program.

"With 10 German centres now open and patients already pre-registered for the final dose cohort, the study is well positioned to generate preliminary Phase 1b data during the fourth quarter of 2026.

"High-risk MDS represents a significant potential indication expansion and commercial opportunity for amsulostat beyond the FDA-supported development pathway in myelofibrosis. Together with the Australian MESSAGE study in lower-risk disease, AZALOX provides the opportunity to evaluate amsulostat across distinct MDS populations and build a broader clinical data package around the asset."

AZALOX is being conducted through the German MDS Study Group under the sponsorship of Heidelberg University, in collaboration with the Coordination Centre for Clinical Studies Heidelberg. The study is financially supported by German Cancer Aid.

The study was initiated following encouraging preclinical research indicating that the combination of amsulostat and a hypomethylating agent may reactivate red blood cell and platelet production. The ongoing clinical study is assessing whether this approach may reduce patients' dependence on blood transfusions and lower the risk of disease progression to acute myeloid leukaemia.

Progress in AZALOX represents an important potential indication expansion for amsulostat beyond myelofibrosis, providing Syntara with the opportunity to establish a broader clinical and commercial profile for the asset across haematological cancers characterised by dysfunction of extracellular matrix and blood cell production.

In parallel with AZALOX, the Australasian Leukaemia & Lymphoma Group (ALLG) is leading the Australian MDS05/D3 MESSAGE study evaluating amsulostat in combination with the oral hypomethylating agent ASTX727 in patients with transfusion-dependent low and intermediate-risk MDS. The MESSAGE study remains in recruitment for its initial dose-escalation cohort, with Syntara anticipating preliminary results during the first half of calendar 2027. The study is intended to complement AZALOX by evaluating amsulostat in a distinct MDS patient population and treatment setting.

** 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. A phase 2a study of SNT-4728 in patients with isolated REM Sleep Behaviour Disorder has reported encouraging preliminary data.

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.

SOURCE:
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