

Media Release

8 July 2025

WHO grants official INN for Syntara's clinical development asset SNT-5505: amsulostat

Syntara Limited (ASX: SNT), a clinical-stage drug development company, today announces that the World Health Organization (WHO) has formally granted the International Non-Proprietary Name (INN) of amsulostat to its advanced clinical development asset SNT-5505.

Commonly known as a generic name, an INN is a globally recognised, unique name for a pharmaceutical substance or active ingredient.

Amsulostat is an innovative oral therapy currently in clinical development for myelofibrosis (MF), a debilitating bone marrow disorder characterised by fibrosis that severely impacts blood cell production.

Recent interim Phase 2 clinical trial results, which demonstrated promising efficacy and an excellent safety profile in combination with ruxolitinib, underscore the potential of amsulostat as a differentiated treatment option for patients with MF who exhibit suboptimal responses to existing therapies.

The designation of an INN represents an important milestone in the drug development process, providing global recognition of amsulostat's unique chemical identity and facilitating clearer communication among healthcare professionals and regulatory bodies worldwide.

Syntara CEO Gary Phillips said: "After very recently being awarded Fast Track Designation by the FDA, the granting of amsulostat as the INN for SNT-5505 is another important step forward, reflecting the drug's unique mechanism of action and clinical promise. We remain focused on advancing amsulostat through clinical development to address significant unmet medical needs in myelofibrosis and other fibrotic diseases."

#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 amsulostat (previously known as SNT-5505 and 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 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.