

Channel 7: August 2023

The following story appeared on 7NEWS August 2023.

When nature delivers new medicine: Our soft tissue sarcoma therapy Yondelis® (trabectedin) has this month been listed on the Pharmaceutical Benefits Scheme for patients with advanced liposarcoma and leiomyosarcoma, but you may be surprised where scientists originally sourced this novel compound.

Specialised Therapeutics Asia to Re-introduce Global Sarcoma Drug to Patients in Singapore, Malaysia and Brunei

Singapore, 9 September 2021: A globally regarded sarcoma therapy that has been shown to improve progression free survival¹ is now being re-introduced in key regions of South-East Asia by independent pharmaceutical company Specialised Therapeutics Asia (STA).

The compound YONDELIS® (trabectedin) will be available to advanced sarcoma patients via their treating oncologists in Singapore, Malaysia and Brunei, following a license agreement between STA and its international pharmaceutical partner, PharmaMar S.A.

YONDELIS has been approved in Singapore, Malaysia and Brunei since 2009 and was previously provided to patients in these regions under a separate

pharmaceutical arrangement with former product licensee, Janssen Products, L. E. Full marketing authorisation has now been formally transferred to STA.

YONDELIS - which has been shown to improve progression-free survival when used subsequent to anthracycline-based therapy for patients with unresectable or metastatic liposarcoma (LPS) or leiomyosarcoma (LMS)¹ - is approved in Singapore and has been available to patients in the United States since 2015,² and in Europe since 2007.³

Malaysian sarcoma specialist Dr Aminudin Rahman Bin Mohd Mydin, Consultant Clinical Oncologist at the KPJ Damansara Specialist Hospital, welcomed the renewed availability of YONDELIS for appropriate patients in South East Asia.

Dr Aminudin commented: "This is exciting news. YONDELIS is an established therapy that has already been extensively used globally to treat advanced sarcoma patients in South East Asia and globally.

"We expect that the reintroduction of this important therapy in key South East Asian regions will provide a new treatment option for many of our patients, as we strive to provide new therapy options and improve outcomes."

STA Chief Executive Officer Mr Carlo Montagner said YONDELIS had been previously available to South East Asian patients and is recognised as a global standard of care therapy.

Mr Montagner commented: "Our company has a strong and extensive foundation in oncology and this product is a valuable inclusion to our therapeutic portfolio. We look forward to working with the sarcoma community in multiple regions of South East Asia to improve access to YONDELIS and ensure that it is considered as a new therapy option for all appropriate patients."

STA markets YONDELIS under an exclusive license arrangement with an international partner, PharmaMar.

Ends.

About Specialised Therapeutics Asia

Headquartered in Singapore, Specialised Therapeutics Asia Pte Ltd (STA) is an international biopharmaceutical company established to commercialise new therapies and technologies to patients throughout South East Asia, as well as in Australia and New Zealand. STA and its regional affiliates collaborate with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life-changing healthcare solutions to patients affected by a range of diseases. Its mission is to provide therapies where there is an unmet need. The company's broad therapeutic portfolio currently includes novel agents in oncology, haematology, neurology, ophthalmology and supportive care. Additional information can be found at www.stbiopharma.com

About PharmaMar

Headquartered in Madrid, PharmaMar is a biopharmaceutical company focused on oncology and committed to research and development, taking its inspiration from the sea to discover molecules with antitumor activity. It is a company seeking innovative products to provide health care professionals with new tools to treat cancer. Its commitment to patients and to research has made it a world leader in the discovery of antitumor drugs of marine origin.

PharmaMar has a pipeline of drug candidates and a robust R&D oncology program. It develops and commercializes YONDELIS[®] in Europe and has other clinical stage programs under development for several types of solid cancers: lurbinectedin (PM1183), PM184 and PM14.

About YONDELIS[®] (trabectedin)

YONDELIS[®] (trabectedin) is a novel, multimodal, synthetically produced antitumor agent, originally derived from the sea squirt, *Ecteinascidia turbinata*. The anti-cancer medicine works by preventing tumor cells from multiplying and is approved in 76 countries in North America, Europe, South America and Asia for the treatment of advanced soft-tissue sarcomas as a single-agent, and in 69 countries for relapsed ovarian in combination with DOXIL[®]/CAELYX[®] (doxorubicin HCl liposome injection).

The approval was based on the results of a pivotal phase 3, randomised, open-label controlled study which evaluated YONDELIS versus dacarbazine in over 500 patients with unresectable or metastatic liposarcoma (LPS) or leiomyosarcoma (LMS) previously treated with an anthracycline and at least one additional chemotherapy regimen. LPS and LMS are subtypes of soft tissue sarcoma (STS) and represent more than 35% of all STS cases.⁴

The median progression-free survival (PFS) among the YONDELIS treatment group was 4.2 months compared to 1.5 months in the dacarbazine treatment group, representing a 45% reduction in the risk of disease progression or death with YONDELIS (HR=0.55; 95% CI: 0.44 - 0.70; p<0.001).¹

Among the 340 patients who received YONDELIS and were included in the safety analysis in the randomised trial, the most common ($\geq 20\%$) adverse reactions were nausea (73%), fatigue (67%), vomiting (44%), constipation (36%), decreased appetite (34%), diarrhoea (34%), dyspnoea (25%), peripheral oedema (24%) and headache (23%). The most common ($\geq 20\%$) laboratory abnormalities were neutropenia (49%), increased alanine transaminase (ALT) (45%), anaemia (39%), increased aspartate aminotransferase (AST) (35%), thrombocytopaenia (30%) and increased blood alkaline phosphatase (20%).¹

About Soft Tissue Sarcoma

Soft tissue sarcoma is a rare type of cancer that forms as a painless lump (tumour) in any one of the soft tissues connecting all the organs and body structures - including fat, muscle, nerves, deep skin tissue, blood vessels and the tissue surrounding joints (synovial tissue). Soft tissue sarcomas commonly develop in the thigh, shoulder and pelvis and may sometimes develop in the abdomen or chest.⁵

Metastatic or locally advanced STS is generally considered incurable, with the mainstay of treatment being systemic chemotherapy. For some patients with limited disease burden however, long-term remission can be achieved through a multimodality approach involving medical, surgical and radiation therapy.⁵

YONDELIS is a registered trademark of PharmaMar SA. YONDELIS is under

license from PharmaMar SA.

Further Enquiries

Emma Power, Corporate Affairs and Communications Manager, Specialised Therapeutics Asia +65 3158 9940 or +61 419 149 525 or epower@stbiopharma.com

References:

1. Demetri G. et al. J Clin Oncol. 2016; 34(8): 786-793
2. Barone A. et al. Clin Cancer Res; 2017; 23(24): 7448-7453
3. YONDELIS (trabectedin) European Medicines Agency Summary of Product Characteristics
4. Cancer Council Victoria Fact Sheet - Soft tissue sarcoma. Available at https://www.cancervic.org.au/cancer-information/types-of-cancer/soft_tissue_cancers/soft-tissue-cancers-overview.html. Last Accessed: October 2019.
5. Bae S. et al. Clin Sarcoma Res. 2016; 6:11