Global Sarcoma Therapy Now Approved for New Zealand Patients

- Globally regarded soft-tissue sarcoma therapy has been approved by Medsafe for New Zealand patients
- YONDELIS® (trabectedin) demonstrates 45% reduction in risk of disease progression or death versus dacarbazine[1]

Singapore and Auckland, New Zealand, 17 February 2023: Independent biopharmaceutical company Specialised Therapeutics (ST) is pleased to announce that its portfolio therapy to treat rare soft tissue sarcomas has now been approved in New Zealand.

Medsafe has approved the use of YONDELIS® (trabectedin) "*for the treatment of patients with unresectable or metastatic liposarcoma or leiomyosarcoma who received a prior anthracycline-containing regimen*".[2]

YONDELIS (trabectedin) is used extensively around the world and has been shown to improve progression free survival[1].

News of the Medsafe registration has been welcomed by oncologists and the New Zealand sarcoma community, who say it means patients whose disease has progressed will have access to a new line of therapy.

"Sarcoma is a relatively rare cancer and treatment options are limited for those with advanced disease," said Associate Professor Jayesh Desai, Medical Oncologist and Deputy Chair of the Australia and New Zealand Sarcoma Association (ANZSA)

"We welcome news that this therapy is formally approved for use in New Zealand and look forward to seeing advanced sarcoma patients being provided additional

benefit.”

And ANZSA Chief Executive Officer Dr Denise Caruso said: “YONDELIS is an established therapy that has already been used extensively around the world to treat advanced sarcoma patients. We welcome formal registration in New Zealand and expect that all eligible New Zealand patients will be provided access to this global treatment option.”

YONDELIS is already approved and has been available to patients in the United States since 2015,[3] and in Europe since 2007.[4] It was approved by Australia’s Therapeutic Goods Administration in 2021.[5]

YONDELIS is made available in New Zealand by independent biopharmaceutical company Specialised Therapeutics Asia (ST) under an exclusive license arrangement with international partner PharmaMar SA.

ST Chief Executive Officer Mr Carlo Montagner commented: “We are pleased to achieve this milestone in New Zealand and look forward to providing patients with sarcoma with another valuable treatment option.

“We will continue working with the sarcoma community in New Zealand to ensure that YONDELIS is available at the earliest opportunity.”

Ends.

About Specialised Therapeutics

Headquartered in Singapore, Specialised Therapeutics (ST) is an international biopharmaceutical company established to commercialise new therapies and technologies to patients in Australia, New Zealand and across South-East Asia. ST 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

PharmaMar is a biopharmaceutical company focused on the research and development of new oncology treatments, whose mission is to improve the healthcare outcomes of patients afflicted by serious diseases with our innovative medicines. The Company is inspired by the sea, driven by science, and motivated by patients with serious diseases to improve their lives by delivering novel medicines to them. PharmaMar intends to continue to be the world leader in marine medicinal discovery, development and innovation. PharmaMar has developed and now commercializes Yondelis® in Europe by itself, as well as Zepzelca® (lurbinectedin), in the US; and Aplidin® (plitidepsin), in Australia, with different partners. In addition, it has a pipeline of drug candidates and a robust R&D oncology program. PharmaMar has other clinical-stage programs under development for several types of solid cancers: lurbinectedin and ecubectedin. Headquartered in Madrid (Spain), PharmaMar has subsidiaries in Germany, France, Italy, Belgium, Austria, Switzerland and The United States. PharmaMar also wholly owns Sylentis, a company dedicated to researching therapeutic applications of gene silencing (RNAi). To learn more about PharmaMar, please visit us at www.pharmamar.com

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 tumour 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.[6] 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, 2] Among the 340 patients who received YONDELIS and were included in the safety analysis in the randomised trial, the most common (≥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 (≥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.[7] 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.[7] Leiomyosarcoma (LMS) is the most common subtype of STS, accounting for approximately 20 to 25% of all newly diagnosed cases.[7] Common sites for LMS include the abdomen, retroperitoneum, larger blood vessels, and

the uterus. It is less common in the extremities compared with other STS subtypes, accounting for 10% to 15% of limb sarcomas.[8] Liposarcoma (LPS) accounts for approximately 10 to 15% of cases of STS. Typical sites of origin include the extremities and retroperitoneum.[9]

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