Global Sarcoma Therapy Now Listed on Pharmaceutical Benefits Scheme

- *YONDELIS® (trabectedin) now PBS listed for Australian patients*
- *Listing described as "wonderful news" for patients living with rare lipo and leiomyo sarcomas*
- *YONDELIS® (trabectedin) demonstrates 45% reduction in risk of disease progression or death versus dacarbazine*[1]

Singapore, 31 July 2023: AUSTRALIAN cancer patients who have been diagnosed with rare soft tissue sarcomas will now have affordable access to a global therapy shown to improve survival, following its listing on the Pharmaceutical Benefits Scheme (PBS).

The therapy YONDELIS® (trabectedin) is a novel anti-tumour agent originally derived from the sea squirt and will be available to eligible patients on the PBS from **August 1.**

It is used extensively around the world and has been shown to improve progression-free survival for patients with liposarcoma and leiomyosarcoma when used after anthracycline-based therapy.[1]

Until today, some patients have paid up to $50,000 to access YONDELIS treatment.

News of the PBS listing is being welcomed by oncologists and the Australian sarcoma community, who say it will alleviate cost of treatment pressures for those patients whose disease has progressed.

Medical oncologist and Scientific Advisory Committee member and Lead of the

ANZSA National Sarcoma Database Dr Susie Bae, said YONDELIS has been available in Europe since 2007 for patients with advanced soft tissue sarcoma, and Australian patients had waited many years for reimbursed access.

“This milestone means patients don’t need to worry about not being able to afford or miss out on an active drug that can potentially buy precious time with their loved ones, by providing disease control and keeping symptoms at bay for longer,” Dr Bae said.

Melbourne patient advocate and mother of two Karen Lurati – herself diagnosed with liposarcoma six years ago – said this listing provided new hope for other patients.

“A PBS listing for YONDELIS is so exciting for those people who may not have been able to afford the treatment before,” she said. “Rare cancers don’t often get (Government) funding or attention. To now have this therapy on the PBS is great progress.

“Patients often feel that they have to go overseas and spend enormous amounts of money on treatments that may not be available in Australia. This can be frustrating and financially crippling. So, for patients to have access to a global therapy in their own country is wonderful news.”

And Rare Cancers Australia (RCA) Chief Executive Richard Vines said he was “delighted with this outcome”, describing the listing as “great news” for patients living with an L-sarcoma.

“For too long, sarcoma patients have been unable to access all therapies which may provide benefit,” he said. Today’s announcement means they can access a PBS funded medicine instead of having to try and find tens of thousands of dollars – if not more – to self-fund a treatment that may give them more time.”

YONDELIS is marketed in Australia by independent pharmaceutical company Specialised Therapeutics, under an exclusive license arrangement with international partner PharmaMar.

ST Chief Executive Officer Carlo Montagner said the PBS listing was a significant milestone for the company.

He commented: “We acquired the YONDELIS rights in 2019 following requests

from key oncology groups and doctors, who had been importing the product at great cost and with complex logistics for those patients diagnosed with these rare cancers.

“This PBS listing is the culmination of a substantive effort by our team together with the oncology community to achieve full regulatory approval and a PBS listing.

“We look forward to continuing our work with the sarcoma community.”

Ends.

Further Inquiries can be directed to ST Communications Manager Emma Power via email epower@stbiopharma.com or on +61 419 149 525.

About Specialised Therapeutics Asia

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. Our mission is to provide therapies that would otherwise not be available to communities in our regions. 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 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 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.[3]

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 (≥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.[6]

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.[4]

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, ecubectedin, PM534 and PM54. It also has a preclinical and clinical program in virology. 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.

References

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