

# Building from a Solid Foundation: The Future of MedTech in Australia

ST has featured in the latest MedTech Sector report published by financial services and corporate advisory firm RSM. Turn to pages 16 and 17 where CEO Carlo Montagner discusses our business model, licensing strategy and future plans. Click on the magazine below to read the article.



---

## Patient Experience - Small Cell Lung Cancer

57 year old Lay Har has never been a smoker and has always considered herself relatively healthy, was shocked when she was diagnosed with Stage 4 Small Cell Lung Cancer in April this year, after experiencing some “discomfort” in her chest. She was scared by her diagnosis but has found support from fellow patients and the 365 Cancer Prevention Society.

Lay Har has shared her experience to mark Lung Cancer Awareness Month.

“For two days in a row, I felt some discomfort in a specific area of my chest, so I went to a polyclinic to get an x-ray. The x-ray revealed a mass in my lungs, and I

was scheduled for more scans at the hospital. It was after all these tests that I received the shocking diagnosis.

I remembered during those bad days, I was feeling scared. I was searching for more information about the cancer, when I stumbled upon the 365 Cancer Prevention Society's Facebook page. I made contact and was referred to one of their social service centres.

I was able to manage better with their help and support, which has included counselling, diet-related advice and regular check-ins from a care leader.

I was also able to speak with other patients going through similar experiences. They inspire me, because they say that overall the experience of going through has made them stronger.

These people give me hope to go on being courageous and to adopt a more positive mindset.

I am on targeted therapy, I take oral medication. I am exercising well, and eating a balanced diet.

Now I am focused on my treatment and hope I can do well and live well. I hope I can share my experience with the other cancer fighters.

It is important to keep a calm, positive attitude and stay busy with enjoyable activities.

Also remember to get enough rest.

Lung cancer can happen to anyone. It is a silent disease with almost no symptoms and is usually only detected in later stages.

I hope to see greater awareness of this cancer, so others can understand the risks.

What gives me hope for the future?

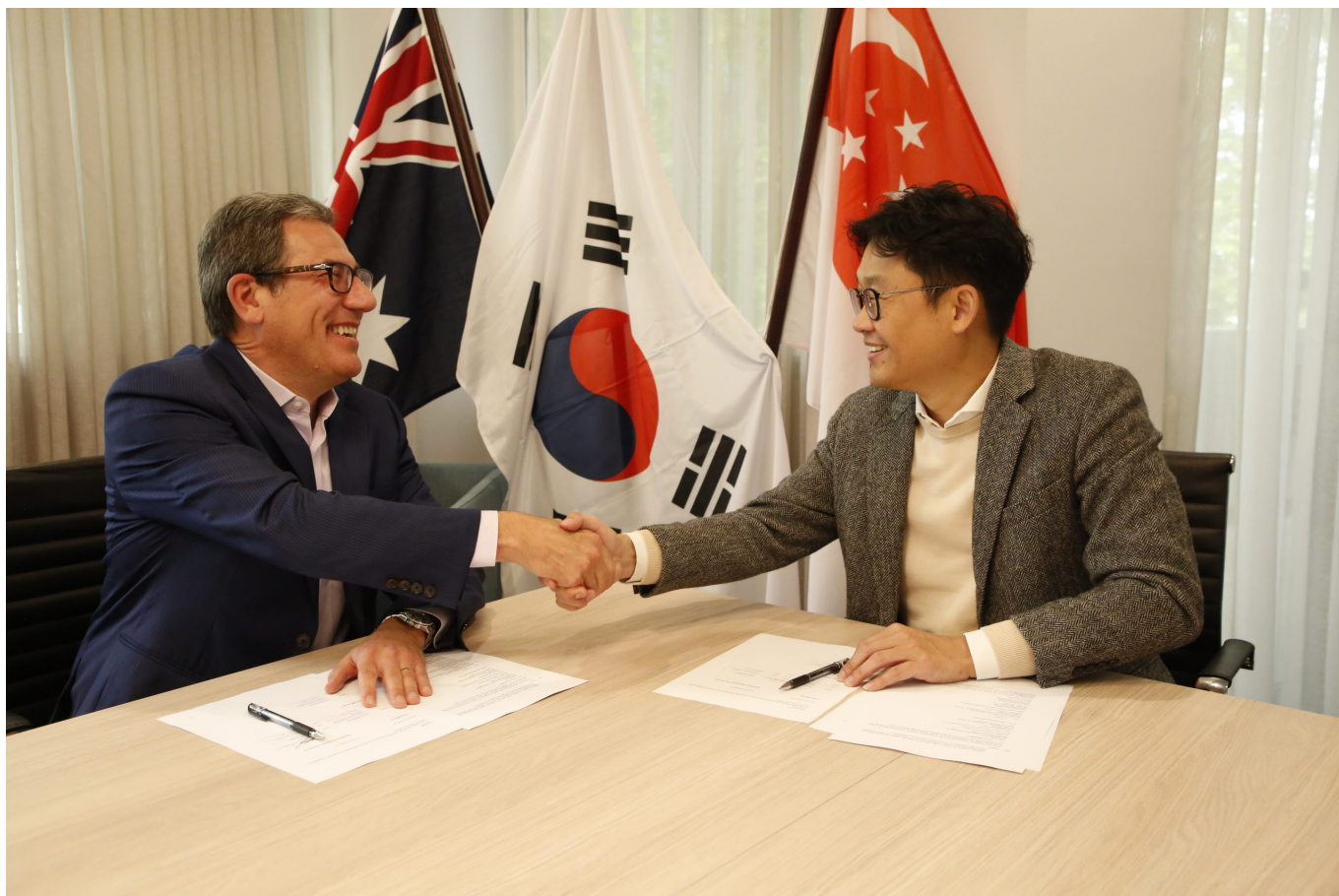
I hope there are new and better treatment options to help those who are diagnosed after me."

---

# Specialised Therapeutics Signs Exclusive License Agreement with CanariaBio for New Ovarian Cancer Therapy

- First ovarian cancer therapy for ST oncology portfolio
- Phase 2 study demonstrated oregovomab in combination with chemotherapy improved progression free survival by ~30 months compared to chemotherapy alone<sup>1</sup>
- Phase 3 results expected in 2025
- Exclusive license for AU, NZ, Singapore, Malaysia, Brunei, Thailand and Vietnam

**Singapore and Seoul, South Korea, 13 October 2023:** Independent biopharmaceutical company Specialised Therapeutics Asia Pte Ltd (ST) has signed a license deal with Korea-based [CanariaBio Inc.](#), acquiring the exclusive license to a new monoclonal antibody therapy for patients with ovarian cancer in Australia, New Zealand and in select Southeast Asian countries.



The therapy, known as oregovomab, is currently in a pivotal phase III international clinical trial known as the FLORA-5 study.<sup>2</sup> This investigation is examining oregovomab in combination with chemotherapy agents carboplatin and paclitaxel for patients with advanced ovarian cancer.

Under the terms of the arrangement, ST will be responsible for all commercial, medical, regulatory and distribution activities for oregovomab in its key territories of Australia, New Zealand, Singapore, Thailand, Vietnam, Brunei and Malaysia. CanariaBio will be responsible for the manufacture and supply of oregovomab to ST.

Announcing the partnership, ST Chief Executive Officer Carlo Montagner said he was pleased CanariaBio had selected ST as a partner for this highly promising therapy.

“ST has a portfolio of anti-cancer therapies targeting multiple solid tumours with the exception of ovarian cancer, and now oregovomab becomes our first ovarian cancer agent,” Mr Montagner said.

“Despite great advances in recent years, there remains a high unmet need in all

our regions to treat this patient population. We look forward to working closely with our new partners at CanariaBio and pending the results of the pivotal Phase III registration study, making oregovomab available to eligible patients.”

CanariaBio Chairman and CEO Michael Na said the company had selected ST for its regional expertise and strong track record commercialising oncology products. Carlo Montagner (Oct 11, 2023 12:11 GMT+11)

“Formalising this agreement is a pivotal moment for our program. This collaboration is more than just a deal - it’s a shared commitment as we develop novel therapies to address unmet medical needs. At CanariaBio, we’ve always believed in the transformative power of partnerships, and teaming up with ST reinforces this belief.” Oregovomab works by targeting and binding specifically to a surface protein known as CA-125 found on the surface of ovarian cancer cells, then activating the patient’s own immune system to respond.<sup>3</sup>

In the Phase 2 study, the addition of oregovomab to chemotherapy yielded a median progression-free survival of 41.8 months compared with 12.2 months with standard chemotherapy alone (HR, 0.46, P=0.0027). The overall survival hazard ratio was 0.35.1 The Phase 3 FLORA-5 study is fully enrolled and ongoing. Final results are expected in 2025.

**Ends.**

**Further enquiries:**

- **ST Senior Manager Communications and Corporate Affairs Emma Power**

+61 419 419 525 or email [epower@stbiopharma.com](mailto:epower@stbiopharma.com)

- **CanariaBio Communications Manager Jacquelyn Choi**

+82 6925 2177 or via email [jacquelyn@canariabio.com](mailto:jacquelyn@canariabio.com)

**About Specialised Therapeutics**

Founded in 2007, Specialised Therapeutics is the region's largest independent specialty pharmaceutical company, providing new therapies and technologies to patients in Australia, New Zealand and across Southeast Asia. Headquartered in Singapore, ST partners with global pharmaceutical, biotech and diagnostic companies to bring novel healthcare opportunities to patients who are impacted by a range of diseases. ST has built a strong track record of success, navigating complex regulatory, reimbursement and commercialisation environments in its diverse regions. The ST mission is to provide specialty therapies where there is an unmet need. The company's broad therapeutic portfolio currently includes novel agents in oncology, haematology, CNS, ophthalmology and supportive care, although it is not confined to these areas. Additional information: [www.stbiopharma.com](http://www.stbiopharma.com)

About CanariaBio Inc. CanariaBio Inc. is a clinical-stage biopharmaceutical company dedicated to the development and commercialization of innovative cancer biotherapeutics. CanariaBio's technology platform includes a portfolio of tumor antigen-specific monoclonal antibodies targeting CA-125, MUC1, PSA, and HER2/neu.

### **About Oregovomab**

Oregovomab is a murine monoclonal antibody directed to the tumor-associated antigen CA-125 that stimulates a host cytotoxic immune response against tumor cells expressing CA-125, a biomarker commonly found in ovarian cancer (OC). In a randomized Phase 2 clinical trial, oregovomab demonstrated a significant improvement in progression-free and overall survival in advanced OC treatment when administered simultaneously with first-line chemotherapy. This promising schedule is currently being investigated in a Phase 3 trial.

### **About FLORA-5 Phase 3 Study**

The Phase 3 clinical trial called FLORA-5/GOG-3035, is a double-blind, placebo-controlled, multicentre clinical study comparing the safety and efficacy of oregovomab versus placebo when administered in combination with specific cycles of a standard six-cycle chemotherapy regimen (paclitaxel and carboplatin)

for the treatment of newly diagnosed patients with advanced epithelial ovarian, fallopian tube or peritoneal carcinoma, in conjunction with optimal debulking surgical resection. The primary and secondary endpoints, for both the adjuvant and neoadjuvant cohorts of this trial, are progression free survival and overall survival, respectively. The FLORA-5 trial is being conducted in collaboration with the Gynecologic Oncology Group Foundation in the US and IQVIA (a clinical research organization). Greater China area clinical trials are conducted in collaboration with OncoVent, a Shenzhen Hepalink Pharmaceuticals Group Company in China, which is also the commercialization license holder of oregovomab for China. Information on the clinical trial can be found on [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

### **References:**

1. Brewer M, et al. Gynecol Oncol. 2020.156(3):523-529
2. ClinicalTrials.gov NCT04498117
3. [www.FLORA-5.com](http://www.FLORA-5.com). Last accessed October 2023.

---

# **Breast Cancer Awareness Month: Meet the Specialist**

**Consultant Clinical Oncologist Dr Aqilah Othman says an ageing population, fewer and later pregnancies, a lack of physical activity, obesity and poor dietary habits may be contributing to a rising incidence of new breast cancer cases across Southeast Asia.**

**To mark Breast Cancer Awareness Month 2023, the Sunway Medical Centre oncologist discusses the incidence of breast cancer in Malaysia as well as the risk and fear of recurrence.**

**Q: How common is breast cancer in Malaysia?**

A: According to the Malaysia National Cancer Registry Report 2012-2016 there were 13,485 breast cancer cases, with an approximate lifetime risk of 1 in 20 women.<sup>1</sup>

The number of breast cancer cases is projected to spike in the near future, and we believe that this could be due to an ageing population, as well as other risk factors including not having children or late pregnancies, a lack of physical activity, obesity, and poor diets, with the consumption of highly processed foods and unregulated supplements.

**Q: What are the chances of a cancer recurrence following the original breast cancer diagnosis?**

A: Up to 10% of women with early breast cancer will have a recurrence after treatment.<sup>2</sup>

The risk is higher for those with genetic mutations or those who have had suboptimal treatment. The biology of the tumour itself - for example, if it is HER2 positive or triple negative - also increases the risk of recurrence. We know that between 30 and 50% of HER2 positive breast cancer patients will relapse within 10 years without HER2 targeted treatment.

**Q: Is the fear of recurrence almost universal and how can this be addressed?**

A: Many women who have been treated for breast cancer are afraid that the cancer is still there, or that it will relapse. This is normal and I think it is a reasonable worry.

However, if this fear becomes an obsession or interferes with normal life activities then this is a serious problem that needs to be addressed.

Women should be assured that they have done whatever they can within their limits by pursuing and completing all recommended treatments prescribed by



their oncologists, as well as modifying other risk factors, for example, increasing physical activity, adopting a healthier diet and lifestyle and paying attention to their mental and emotional wellbeing.

Some identified distraction strategies like work, exercise, meditation or praying can help to curb negative thoughts as soon as they start.

Support from family, friends, support groups and therapists can also help, but I find that many times it is the acceptance of the diagnosis by the individuals themselves, knowing that they are not the only ones and interacting with others who are in similar situations is effective.

### **What are the median survival rates of breast cancer in Southeast Asia?**

A: There are big differences within and between each Southeast Asian country, however it is known that there are more late presentations, less treatment uptake and adherence leading to poorer outcomes in this region, compared to our western counterparts.

In some regions there is simply a lack of resources to identify and treat cancer optimally.

On the other hand, there are regions that have underutilised state of the art facilities and have less than ideal uptake of early detection programmes or timely treatment.

### **Q: Why is this the case?**

A: Barriers include the inability to recognise or acknowledge symptoms, poor decision-making skills, lack of self and body empowerment, belief in alternative therapies and perceived cancer fatalism. Some patients believe that death is inevitable when cancer is diagnosed, and this can lead to delayed treatment even when diagnosed early.

### **Q: Why should women in Southeast Asia be vigilant so cancer is detected**

**early?**

A: Early detection and timely access to optimal treatments can save lives and improve outcomes. There is still a long way to go in integrating the psychosocial and cultural beliefs of the local population. We must continue to dispel myths, build awareness and address these to close the cancer gap.

## **References**

1. Azizah AM et al. Malaysia National Cancer Registry Report. 2012-2016
  2. Balasundram Set al. Asian Pac J Cancer Prev.19(9): 2409-2415, 2018.
- 

# **World Orphan Drug Alliance Welcomes Specialised Therapeutics**

- *SEA's largest independent specialty pharma company Specialised Therapeutics (ST) has joined global pharma consortium committed to collaborating to provide new specialist medicines for rare diseases*
- *ST to represent WODA in Australia, New Zealand and across Southeast Asia (ANZSEA)*
- *World Orphan Drug Alliance (WODA) now spans 152 countries.*
- *WODA offers a 'one-stop' solution for biotech companies seeking to commercialise products across global markets.*

*Dubai, Moscow, Ljubljana, Sao Paulo, Zurich, Shanghai, Singapore,*

**September 8, 2023** - Independent biopharmaceutical company Specialised Therapeutics (ST) has joined World Orphan Drug Alliance (WODA), an international consortium of pharmaceutical companies, established to improve patient access to new treatments for rare diseases.

WODA operates by identifying biotech and pharmaceutical companies with new therapies for treating rare diseases that may not be available to patients in many regions and providing these companies with the opportunity to commercialise their novel therapies in member countries.

WODA Chairman Patrick Jordan commented: *"It's truly inspiring and exciting to witness the alliance's expansion. WODA's commercial presence has now extended to an impressive number of 152 markets covered by nine like-minded pharmaceutical companies, providing extensive global outreach with a local focus. Our members are experienced and high-performance commercialisation companies, each being an expert in their own region."*

He added: *"Through seamless collaboration among our members, we provide our partners with a single platform for full commercialisation of medicines, tailored to both partner and product needs."*

Specialised Therapeutics CEO Carlo Montagner said WODA's mission to address the unmet medical needs of local communities with novel therapies strongly aligned with ST's vision.

*"We firmly believe that patients in our regions should have access to the same innovative treatments as patients have in larger markets like the US and Europe,"* Mr. Montagner commented.

*"We now look forward to working with our WODA peers to ensure timely and equitable access to new therapies that may improve outcomes. I am confident that our WODA membership will further expand our capabilities, enabling us to provide additional therapies where there is an unmet need."*

###

## **About Specialised Therapeutics**

Founded in 2007, Specialised Therapeutics is the region's largest independent specialty pharmaceutical company, providing new therapies and technologies to patients in Australia, New Zealand and across Southeast Asia. Headquartered in Singapore, ST partners with global pharmaceutical, biotech and diagnostic companies to bring novel healthcare opportunities to patients who are impacted by a range of diseases. ST has built a strong track record of success, navigating complex regulatory, reimbursement and commercialisation environments in its diverse regions. The ST mission is to provide specialty therapies where there is an unmet need. The company's broad therapeutic portfolio currently includes novel agents in oncology, haematology, CNS, ophthalmology and supportive care, although it is not confined to these areas.

Additional information: [www.stbiopharma.com](http://www.stbiopharma.com)

## **About WODA**

The World Orphan Drug Alliance (WODA) is a global alliance of commercial distributors focused on providing access to treatments for rare diseases and specialty medicines in complex and underserved markets around the world. WODA aims to provide comprehensive support to pharmaceutical and biotech companies with rare disease, oncology, and highly specialized therapeutics portfolio, starting from Named Patient Programs through to full commercialization.

Additional information: [www.woda-alliance.com](http://www.woda-alliance.com)

## **About other WODA members**

- [EffRx Pharmaceuticals](#) is a Switzerland based company focused on the late-stage development and commercialization of prescription medications for niche and orphan indications.
- [Medis](#) based in Slovenia is the commercialization partner of choice for innovative pharmaceutical and biotech companies seeking strong business growth in Central and Eastern Europe.
- [Orpharm](#) is a Moscow based full-service distributor covering Russia and the Commonwealth of Independent States (CIS).
- [OrphanDC](#) based in Brazil acts as a partner for biotech companies in

Latin America. They focus on supporting their clients from the clinical development stage throughout the product lifecycle.

- [Vector Pharma](#) is a Dubai based full-service distributor covering Middle East, North Africa and Turkey.
- The Greater China region is covered by [RareStone Group](#), which aims to become the leading company supporting the rare disease community in China.
- Founded in 1921, [CTS](#) is among Israel's leading pharmaceutical companies and is well-known for its strong capabilities in local access, distribution, and marketing of high-end therapies.
- [Path Pharma](#) is a full-service distributor in Greece, Cyprus, and Malta. Founded by industry experts, Path Pharma has expertise in local market access, medical support, and marketing and sales, with focus on rare diseases, highly specialized therapeutics, and oncology.

**Media contact:**

Emma Power

+65 3158 9940, +61 419 149 525

[epower@stbiopharma.com](mailto:epower@stbiopharma.com)

Tina Vojnovic

[tina.vojnovic@woda-alliance.com](mailto:tina.vojnovic@woda-alliance.com)

+386 41 744 735

---

# Specialised Therapeutics Acquires Commercialisation Rights to New

# Oral MND Therapy

Singapore and Tilburg, Netherlands, August 28 2023: Independent biopharmaceutical company Specialised Therapeutics Asia Pte Ltd (ST) will partner with Netherlands based biotechnology company Treeway BV to commercialise a new therapy to treat Amyotrophic Lateral Sclerosis (ALS) - the most common form of Motor Neurone Disease (MND) - in Australia and New Zealand.

The therapy is known as TW001 and is a unique oral formulation of edaravone which works by reducing the oxidative damage associated with neuron death in ALS.<sup>1</sup> TW001 is currently being evaluated in the pivotal ADORE phase III registration study at almost 40 global sites.<sup>2</sup>

Australian neurologist Associate Professor Susan Mathers said around 2000 people were living with MND at any one time in Australia, and an oral therapy like edaravone presented the opportunity for patients to be managed at home.

Associate Professor Mathers commented: "Better disease modifying therapies are urgently needed to slow and potentially halt this disease. Oral therapies like edaravone present the opportunity for a simple to manage therapy which can be taken at home and monitored through each person's local health care provider."

And key patient advocacy body MND Australia is also welcoming the potential for this new oral treatment option.

Executive Director, Research Gethin Thomas commented: "Oral edaravone would complement the recent approval of intravenous edaravone in Australia and broaden the patient base able to access treatment."

Under the terms of the licensing agreement, ST will be responsible for all marketing, regulatory and distribution activities of TW001 for ALS/MND in Australia and New Zealand.

Announcing the partnership, ST Chief Executive Officer Carlo Montagner said TW001 was the first central nervous system (CNS) therapy to be included in the company's therapeutic portfolio and the arrangement was further endorsement of ST's regional capabilities and focus on making available in this region unique

therapies that would otherwise not be accessible.

“We are delighted to partner with Treeway as this promising treatment progresses through the final stages of the pivotal global registration ADORE study,” he said. “We look forward to working with the wider MND community, who are determined to access new therapies to treat this terrible disease. “While there is still no cure for MND, we remain hopeful that new therapies such as TW001 may help to slow disease progression and improve outcomes.”

Treeway CEO Inez de Greef commented: “This important therapy has shown very encouraging results in all studies to date. We look forward to further results from the ADORE study and then working with ST to make our therapy available for all eligible patients in Australia and New Zealand who may benefit. ST is focussing on bringing new therapies to the market for diseases with a high medical need and therefore ST fits well as a licensing partner for Treeway.”

**Ends.**

### **About Specialised Therapeutics**

Headquartered in Singapore, Specialised Therapeutics Asia Pte Ltd (ST) is an international biopharmaceutical company established to commercialise new therapies and technologies to patients throughout Southeast Asia, as well as in Australia and New Zealand. 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](http://www.stbiopharma.com).

### **About Treeway**

Treeway is a clinical-stage biotechnology company with a mission to develop therapies to cure ALS and other neurodegenerative diseases. Founded in 2012 by two ALS patients, Treeway is committed to developing the neurodegenerative

disease drugs of tomorrow. Treeway's research and development portfolio has a strong focus on ALS and Alzheimer's Disease and is continuously looking to expand the therapeutic targets within the neurodegenerative diseases arena.

Treeway, Therapy development inspired by patients

[www.treeway.nl](http://www.treeway.nl)

## **About ALS<sup>3</sup>**

Amyotrophic Lateral Sclerosis (ALS), the most frequent motor neuron disease, is a progressive neurodegenerative disease of motor neurons in the brain and spinal cord, resulting in progressive paralysis, with death typically within 2 to 5 years of diagnosis.

ALS is a rare disease that typically occurs in people between 40-70 years old, slightly more men than women. It is caused by a multitude of factors: 10-15% of cases may have a genetic/family link, while 85-90% are considered sporadic, with no known cause.

## **References:**

1. AlzForum Foundation Inc. <https://www.alzforum.org/therapeutics/edaravone>
2. Clinicaltrials.gov ADORE Study (NCT05178810)
3. Masrori and Van Damme; Amyotrophic lateral sclerosis: a clinical review. European Journal of Neurology 2020, 27: 1918- 1929

## **Further Enquiries:**

Aster van Oordt  
Treeway Communication Manager  
Email: [info@treeway.nl](mailto:info@treeway.nl)

Emma Power  
Specialised Therapeutics Communications Manager



M: +61 419 149 525  
epower@stbiopharma.com

---

# 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<sup>1</sup>*

**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.<sup>1</sup>

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](mailto: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](http://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.<sup>3</sup>

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).<sup>1</sup>

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%), thrombocytopenia (30%) and increased blood alkaline phosphatase (20%).<sup>1</sup>

## **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.<sup>6</sup>

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.<sup>4</sup>

## **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<sup>®</sup> in Europe by itself, as well as Zepzelca<sup>®</sup> (lurbinectedin), in the US; and Aplidin<sup>®</sup> (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](http://www.pharmamar.com).

## **References**

1. Demetri G. et al. J Clin Oncol. 2016; 34(8): 786-793
  2. Australian Institute of Health and Welfare data on file 2022
  3. Toro JR, et al. Int J Cancer. 2006; 119:2922-2930
  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](https://www.cancervic.org.au/cancer-information/types-of-cancer/soft_tissue_cancers/soft-tissue-cancers-overview.html)
- 

## **ST to Commercialise New Anti-PD1 Antibody**

Specialised Therapeutics Asia will partner with CTTQ-Akeso to commercialise a new immuno-oncology therapy in Australia, Singapore and across Southeast Asia.

---

## **Cholangiocarcinoma: Understanding This Rare Liver Disease**

This article is contributed by Dr Choo Su Pin, a senior medical oncologist at Curie Oncology who specialises in gastrointestinal cancers.

---

# Thailand Office Opened

Specialised Therapeutics is thrilled to announce the official opening of its Thailand office, as we continue our mission to provide specialist therapies to patients across South East Asia. We are determined to ensure our medicines reach as many eligible patients as possible - particularly in oncology, with almost 200,000 Thai residents diagnosed with cancer every year (\*Globocan 2020).