Specialised Therapeutics Signs Exclusive Agreement with Ascendis Pharma A/S for Distribution and Commercialisation of Three Endocrinology Therapies in Australia and Select South-East Asia Countries

- Agreement between Ascendis Pharma A/S and ST is for the exclusive distribution and commercialisation of three Ascendis Pharma endocrinology therapies
- Two of the therapies are already internationally approved, the third is in development following successful Phase 2 data
- ST's exclusive distribution agreement covers Australia, New Zealand, Singapore, Malaysia, Brunei, Thailand and Vietnam

Singapore 8 January 2024: Independent biopharmaceutical company Specialised Therapeutics Asia Pte Ltd (ST) has added three new endocrinology therapies to its specialist portfolio, following an exclusive distribution agreement with Danish company Ascendis Pharma A/S (NASDAQ: ASND).

Under the terms of the agreement, ST will commercialise Ascendis Pharma's weekly injectable paediatric human growth hormone treatment **SKYTROFA™** (lonapegsomatropin), hypoparathyroidism treatment **YORVIPATH™** (palopegteriparatide) and investigational achondroplasia therapy **TransCon™ CNP** (navepegritide).

The agreement spans ST's key regions of Australia, New Zealand, Singapore, Malaysia, Brunei, Thailand, and Vietnam.

Two of the products included in this agreement are already internationally approved:

- Once-weekly SKYTROFA is a human growth hormone (hGH) approved in the United States ***for the treatment of paediatric patients aged >1 years weighing >11.5 kg with growth failure due to inadequate secretion of endogenous growth hormone (GH)***[1] and in the European Union ***for growth failure in children and adolescents aged from 3 to 18 years due to insufficient endogenous growth hormone secretion (growth hormone deficiency [GHD]).***[2]
- YORVIPATH is a first-in-class parathyroid hormone (PTH) replacement therapy to treat chronic hypoparathyroidism, a rare and potentially serious condition where the body produces no or abnormally low levels of PTH. It is approved in the European Union ***for the treatment of adults with chronic hypoparathyroidism.***[3]

The third product – TransCon CNP – is in development by Ascendis Pharma for the treatment of achondroplasia (ACH), the most common genetic form of skeletal dysplasia and resulting disproportionate short stature, following successful Phase 2 trial results.[4]

Australian endocrinologist Dr Veronica Preda noted that YORVIPATH would be the first specialist therapeutic option for Australian patients living with hypoparathyroidism.

“Hypoparathyroidism can seriously impact quality of life and has potentially life-threatening consequences,” Dr Preda said.

“To have an option that is able to treat the underlying cause of the disease, moving beyond standard oral calcium and active Vitamin D, is a great step forward.”

Announcing the partnership, ST Chief Executive Officer Carlo Montagner said this agreement was an important company milestone, signalling ST’s expansion into both endocrinology and paediatric medicine.

Mr Montagner commented: “We are delighted to have been selected as Ascendis Pharma’s exclusive partner for commercialising their portfolio in Oceania and

these South-East Asia countries and look forward to launching these critical endocrinology products in our regions as soon as possible.

“All three products are valuable inclusions to our broad therapeutic pipeline and our international business, as we continue to leverage our substantial experience commercialising specialist medicines across multiple regions.

“We look forward to working with endocrinologists across our territories to make these endocrine therapies available to all eligible patients who may benefit.”

Ascendis Pharma Executive Vice President and Chief Commercial Officer Camilla Harder Hartvig said ST had been selected to launch the endocrinology portfolio in these countries based on its strong track record commercialising specialist products in multiple regions.

“We are delighted to partner with Specialised Therapeutics to broaden the reach of our endocrinology rare disease portfolio, contributing to our shared goal of making a meaningful difference for patients facing unmet medical needs,” she said.

Ends.

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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, neurology, endocrinology, ophthalmology and supportive care, although it is not confined to these areas. ST is a member of the World Orphan Drug Alliance (WODA).

Additional information: **www.stbiopharma.com**

About Ascendis Pharma

Ascendis Pharma is applying its innovative TransCon technology platform to build a leading, fully integrated biopharma company focused on making a meaningful difference in patients' lives. Guided by its core values of patients, science and passion, the company uses its TransCon technologies to create new and potentially best-in-class therapies. Please visit https://ascendispharma.com to learn more.

About SKYTROFA (lonapegsomatropin)

SKYTROFA™ (lonapegsomatropin, developed as TransCon™ hGH) is a prodrug of somatropin, designed to provide sustained release of unmodified somatropin. The unmodified, unbound somatropin released from lonapegsomatropin has the same 191 amino acid sequence and size as endogenous GH.[5] TransCon hGH is approved and marketed as SKYTROFA (lonapegsomatropin-tcgd) in the United States[1] and as SKYTROFA (lonapegsomatropin) in the European Union[2] as a once-weekly treatment for children and adolescents with GHD.

SKYTROFA single-use, prefilled cartridges are manufactured in nine dosage strengths, allowing for convenient dosing flexibility. They are designed for use only with the SKYTROFA Auto-Injector and may be stored at room temperature for up to six months. The recommended dose of SKYTROFA for treatment-naïve patients and patients switching from daily somatropin is 0.24 mg/kg body weight, administered once weekly.[1,2] The dose may be adjusted based on the child's weight and insulin-like growth factor-1 standard deviation score (IGF-1 SDS).[2]

TransCon hGH was studied in over 300 children with GHD across the Phase 3 program, which consisted of the Height Trial[5] (for treatment-naïve patients), the Flight Trial[6] (for treatment-experienced patients), and the Enlighten Trial[7] (a long-

term extension trial). Patients who completed the Height or Flight Trials were able to continue in Enlighten, with some on lonapegsomatropin treatment for over four years.

Ascendis Pharma is also conducting the ongoing global Phase 3 Foresight Trial of TransCon hGH in adults with GHD.[8]

About Paediatric Growth Hormone Deficiency

Paediatric GHD is a serious orphan disease caused when the pituitary gland does not produce enough GH. Children with GHD are not only characterised by short stature; they also may experience metabolic abnormalities, psychosocial challenges, and an overall poor quality of life. For decades, the standard of care for GHD has been a daily subcutaneous injection of hGH to improve growth and overall endocrine health.

About YORVIPATH (palopegteriparatide)

YORVIPATH™ (palopegteriparatide, developed as TransCon™ PTH) is a once-daily prodrug with sustained release of active PTH approved by the European Union as a PTH replacement therapy for the treatment of adults with chronic hypoparathyroidism. Treatment should be initiated and monitored by physicians or qualified healthcare professionals experienced in the diagnosis and management of patients with hypoparathyroidism.[3]

TransCon PTH met all primary and key secondary endpoints in the Phase 3 Pathway Trial, *demonstrating a response rate of 78.7% compared to 4.8% for control (p-value <0.0001) for the primary composite endpoint, and statistically significant improvements compared to control on all key secondary endpoints, which included measures evaluating patient-reported disease symptoms and impacts.*[9]

About Hypoparathyroidism

Hypoparathyroidism is an endocrine disease caused by insufficient levels of PTH, the primary regulator of calcium/phosphate balance in the body, acting directly on bone and kidneys and indirectly on intestines. Hypoparathyroidism is considered chronic if it persists >6 months following surgery. Individuals with

hypoparathyroidism may experience a range of severe and potentially life-threatening short-term and long-term complications, including neuromuscular irritability, renal complications, extra-skeletal calcifications, and cognitive impairment.[9]

About TransCon CNP (navepegritide)

TransCon™ CNP (navepegritide) is an investigational long-acting prodrug of C-type natriuretic peptide (CNP), designed to provide continuous exposure of CNP at safe, therapeutic levels, via a single, weekly subcutaneous dose, for the treatment of children with ACH.[4]

The Phase 2 Accomplish Trial, a randomised, double-blind, placebo-controlled, dose-escalation trial evaluating the safety and efficacy of once-weekly TransCon CNP compared to placebo in prepubertal children with ACH aged 2 to 10 years old, met its primary objectives, and demonstrated that TransCon CNP at 100 µg/kg/week was superior to placebo for the primary efficacy endpoint of annualised growth velocity (AGV) at 52 weeks[4].

All 57 randomised children completed the blinded portion of Accomplish and are currently continuing in the open label extension at the 100 µg/kg/week dose[4]. Ascendis Pharma recently confirmed that these 57 clinical trial patients have all completed one year of treatment with TransCon CNP at 100 µg/kg/week, and announced that TransCon CNP is the first investigational product to demonstrate improvements in health-related quality of life and disease impacts in children with ACH.[10]

About Achondroplasia

Achondroplasia is the most common genetic form of skeletal dysplasia and resulting disproportionate short stature, caused by a genetic mutation in the fibroblast growth factor receptor 3 (FGFR3). This leads to an imbalance between the stimulatory and inhibitory signaling pathways involved in regulating bone growth. People living with ACH may experience serious complications and comorbidities due to inhibited skeletal development. Complications may include sleep apnoea and respiratory problems, chronic back and leg pain from lower spine impingement, and sudden infant death from compression of the brain stem.

Chronic ear infections due to eustachian tube problems can lead to hearing loss and speech delay. Children with ACH may also experience social and emotional challenges.

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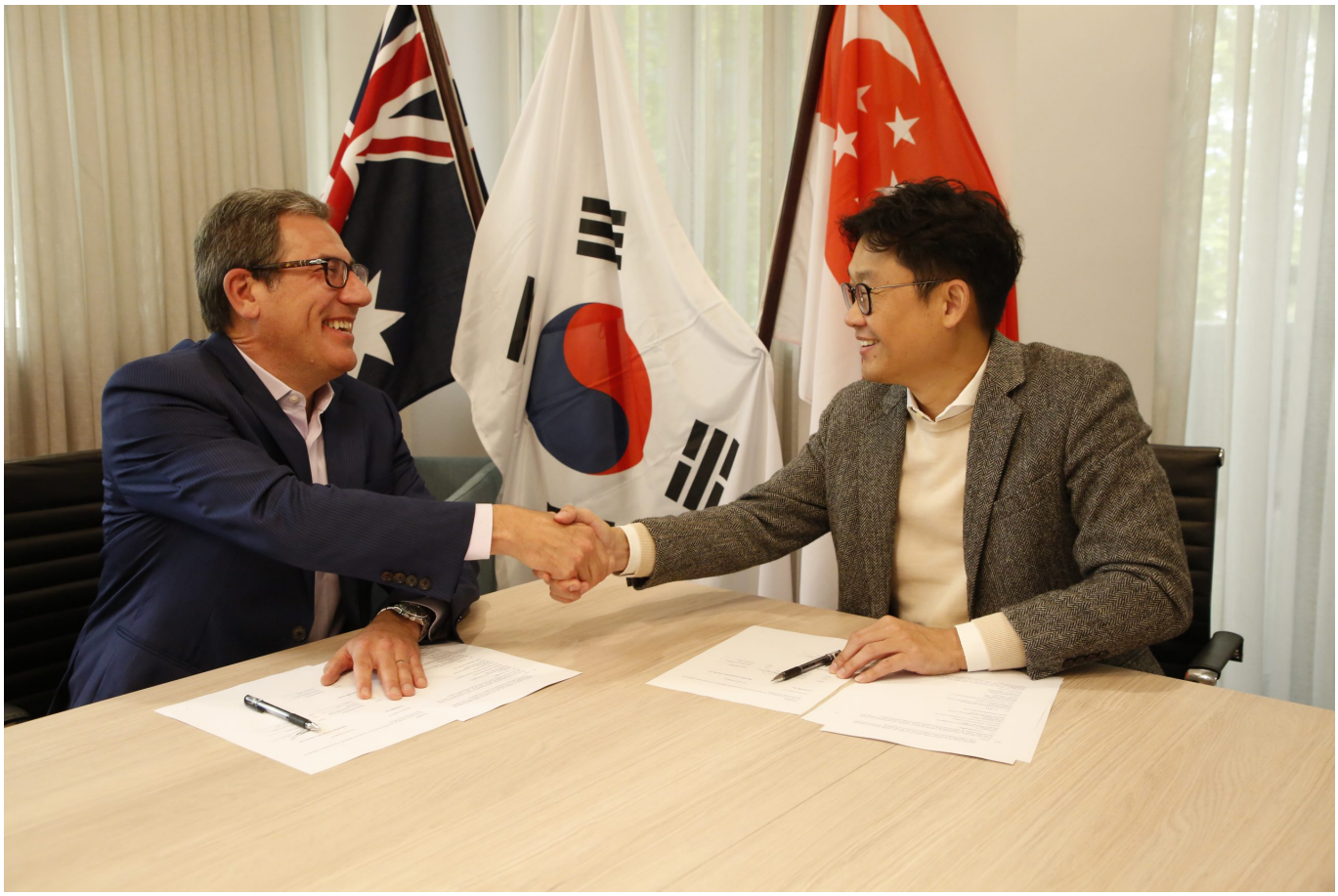
Specialised Therapeutics Signs

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[1]
- 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.[2] 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.[3]

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.

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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

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

References:

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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."

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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**

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**

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.

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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.[1] TW001 is currently being evaluated in the pivotal ADORE phase III registration study at almost 40 global sites.[2]

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.

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 commited 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

About ALS[3]

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.

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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.

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Lymphoma Therapy Now Approved for Australian Patients with Diffuse Large B-cell Lymphoma

MINJUVI® (tafasitamab) provisionally approved by Therapeutic Goods Administration[1]

Recent five-year follow-up data from Phase 2 L-MIND investigation showed patients treated with MINJUVI had prolonged, durable responses[2]

Singapore, 28 June 2023: Independent biopharmaceutical company Specialised Therapeutics (ST) is pleased to announce that a new therapy to treat the most common type of non-Hodgkin lymphoma in adults – diffuse large B-cell lymphoma – is now approved for use in Australia.

The Therapeutic Goods Administration (TGA) has provisionally approved MINJUVI® (tafasitamab) ***"in combination with lenalidomide followed by MINJUVI monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT)".***[1]

Australian lymphoma specialist and current chair of the Australasian Lymphoma Alliance, Professor Chan Cheah, said the MINJUVI approval was a great step forward for patients who had been diagnosed with DLBCL and relapsed, as the MINJUVI regimen provides an opportunity for longer-term disease management.

“I think it is great news for patients,” Professor Cheah said. “We do have chemotherapy options and we cure about two-thirds of patients using that approach. Unfortunately, a substantial proportion of patients either don’t respond to chemotherapy, or the disease comes back after chemotherapy, and they need better treatments.”

MINJUVI, a CD19-targeting immunotherapy that works by attaching to a protein on the surface of B-cell lymphoma cells, stimulating an immune response against the lymphoma, is also approved in the United States [as Monjuvi® (tafasitamab-cxix)], Great Britain, Canada, Europe and other countries.

Professor Cheah added: “Access to novel immune therapies like MINJUVI is really important for Australian patients. Apart from CAR-T cell therapies – and these are only applicable to a certain proportion of patients with DLBCL – there have been no novel therapies for relapsed DLBCL approved in Australia. MINJUVI has a favourable side effect profile and (combined with lenalidomide) has demonstrated a high response rate in patients with relapsed disease. We now need to see it listed on the Pharmaceutical Benefits Scheme.”

MINJUVI has been approved via a provisional regulatory pathway, with the TGA participating in the Modified Project Orbis initiative to accelerate availability to Australian patients. The approval was based on data from the Phase 2 L-MIND study, an open label, multi-center single arm study which evaluated its safety and efficacy in combination with lenalidomide as a treatment for patients with relapsed or refractory DLBCL who were not eligible for ASCT.[1,3]

Continued approval for this indication depends on verification and description of clinical benefit in the confirmatory Phase 3 frontMIND study which has completed enrollment.[4]

Recently, five-year follow up data were presented which showed that MINJUVI plus lenalidomide followed by MINJUVI monotherapy provided prolonged, durable responses in adult patients with relapsed or refractory DLBCL. The overall

response rate (ORR) was 57.5% with a complete response (CR) observed in 41.2% of patients, and a partial response (PR) in 16.2% of patients. The median overall survival was 33.5 months and median progression-free survival (PFS) was 11.6 months.[2] The most common adverse reactions with MINJUVI are infections (73%), neutropenia (51%), asthenia (40%), anaemia (36%), diarrhoea (36%), thrombocytopenia (31%), cough (26%), oedema peripheral (24%), pyrexia (24%), decreased appetite (22%). The most common serious adverse reactions were infection (26%) including pneumonia (7%), and febrile neutropenia (6%).[1]

ST Chief Executive Officer Mr. Carlo Montagner said securing TGA approval was a key regulatory milestone for the company, noting that the therapy was synergistic with the company's mission to provide therapies that addressed unmet needs in rare patient populations.

"We are delighted to successfully register MINJUVI for Australian patients and look forward to working with the lymphoma community to ensure it is available at the earliest opportunity," he said.

ST markets MINJUVI under an exclusive distribution arrangement with international partner Incyte (NASDAQ: INCY).

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 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

About Diffuse Large B-cell Lymphoma (DLBCL)

DLBCL is the most common type of non-Hodgkin lymphoma in adults worldwide[5], characterised by rapidly growing masses of malignant B-cells in the lymph nodes, spleen, liver, bone marrow or other organs. It is an aggressive disease with about 40% of patients not responding to initial therapy or relapsing thereafter[5], leading to a high medical need for new, effective therapies[6], especially for patients who are not eligible for an autologous stem cell transplant in this setting.

About L-MIND

The L-MIND trial was a single arm, open-label Phase 2 study (NCT02399085) investigating the combination of tafasitamab and lenalidomide in patients with relapsed or refractory diffuse large B-cell lymphoma who had at least one, but no more than three, prior lines of therapy, including an anti-CD20 targeting therapy (e.g., rituximab), who were not eligible for high-dose chemotherapy or refused subsequent autologous stem cell transplant. The study's primary endpoint was overall response rate. Secondary outcome measures included duration of response, progression-free survival and overall survival. In May 2019, the study reached its primary completion. For more information about L-MIND, visit https://clinicaltrials.gov/ct2/show/NCT02399085.

About MINJUVI® (tafasitamab-cxix)

Tafasitamab is a humanized Fc-modified CD19 targeting immunotherapy. In 2010, MorphoSys licensed exclusive worldwide rights to develop and commercialize tafasitamab from Xencor, Inc. Tafasitamab incorporates an XmAb® engineered Fc domain, which is intended to lead to a significant potentiation of Antibody-Dependent Cell-Mediated Cytotoxicity (ADCC) and Antibody-Dependent Cellular Phagocytosis (ADCP), thus aiming to improve a key mechanism of tumor cell killing.

MINJUVI known as Monjuvi® (tafasitamab-cxix) in the United States is approved by the U.S. Food and Drug Administration in combination with lenalidomide for the treatment of adult patients with relapsed or refractory DLBCL not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT). This indication is approved underaccelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

In Europe, Minjuvi® (tafasitamab) received conditional marketing authorization in combination with lenalidomide, followed by Minjuvi monotherapy, for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT).

Tafasitamab is being clinically investigated as a therapeutic option in B-cell malignancies in several ongoing combination trials.

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New Therapy for Rare Gastrointestinal Stromal Tumours Approved in Singapore

- *Singapore's Health Sciences Authority (HSA) has approved QINLOCK® (ripretinib) for the treatment of patients with 4th line GIST*
- *QINLOCK significantly reduced the risk of disease progression or death by 85% and showed clinically meaningful overall survival in the INVICTUS Phase 3 Study[1,2]*

Singapore, 8 May 2023: Independent biopharmaceutical company Specialised Therapeutics Asia (ST) is pleased to announce that a new therapy to treat rare gastrointestinal stromal tumours (GIST) shown to improve survival has been approved for use in Singapore.

The therapy, QINLOCK (ripretinib) is now approved by the Health Sciences Authority (HSA) "***for the treatment of adult patients with advanced gastrointestinal stromal tumours (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib, sunitinib, and regorafenib***".

Singapore-based senior consultant in medical oncology Dr Richard Quek said QINLOCK represented a major treatment advancement for patients with advanced GIST.

“Since 2013, despite multiple attempts and studies, no therapy was shown to be effective for 4th line GIST patients whose cancers have progressed on existing treatment, until the discovery of QINLOCK,” Dr Quek said.

In the pivotal INVICTUS study that led to QINLOCK’s approval, QINLOCK was shown to significantly delay cancer progression.

“This approval in Singapore clearly provides an opportunity for us to improve the outcomes of our GIST patients who are refractory to the current existing treatment.”

QINLOCK is an oral medication used to treat GIST in people who have received at least three prior treatments. It belongs to a drug class called tyrosine kinase inhibitors and works by blocking specific tumour proliferation pathways.[2]

A pivotal Phase 3 clinical trial of QINLOCK – the INVICTUS study – demonstrated that QINLOCK was able to significantly reduce the risk of disease progression by 85% (hazard ratio of 0.15, $p<0.0001$) with a median progression-free survival of 6.3 months in patients administered QINLOCK, compared to 1.0 month in the placebo arm.[1] QINLOCK was associated with clinically meaningful overall survival of 15.1 months vs 6.6 months and reduced the risk of death by 64% (hazard ratio of 0.36). The objective response rate by Blinded Independent Central Review using modified Response Evaluation Criteria in Solid Tumors (RECIST) was 9.4% with QINLOCK vs 0.0% with placebo ($p=0.0504$).[1,3]

In addition, in a long-term follow up analysis of the INVICTUS trial, patients in the QINLOCK arm demonstrated a median overall survival of 18.2 months compared to 6.3 months in the placebo arm and reduced the risk of death by 59% (hazard ratio of 0.41).The objective response rate was 11.8% with QINLOCK vs 0.0% with placebo.[3]

ST Chief Executive Officer Carlo Montagner said the Singapore approval followed the recent approval of QINLOCK in New Zealand, as well as regulatory and

reimbursement approval in Australia.

“Achieving these critical regulatory milestones is testament to the dedication of our regulatory teams to make QINLOCK available to all eligible patients in Singapore who are impacted by this rare gastrointestinal cancer.”

ST commercialises QINLOCK in Singapore under an exclusive distribution agreement from US based Deciphera Pharmaceuticals.

Further Inquiries can be directed to ST Senior Manager Communications and Corporate Affairs Emma Power on + 65 31589910 epower@stbiopharma.com

About GIST

Gastrointestinal stromal tumour (GIST) is a cancer affecting the digestive tract or nearby structures within the abdomen, most often presenting in the stomach or small intestine. GIST growth usually begins in the connective tissue in the wall of the affected organ and grows outwards. The common location of GIST is in the stomach (50 to 60%) and small intestines (30 to 40%) but can occur in any site in the digestive system. Other possible GIST sites are the oesophagus, rectum, and colon. GIST cases are rare and estimated to cause between 0.1% and 3% of GI cancer. The risk of GIST diagnosis increases with age, with GIST incidence peaking among people in their fifties and sixties.[4]

About QINLOCK (ripretinib)

QINLOCK is a switch-control tyrosine kinase inhibitor that was engineered to broadly inhibit KIT and PDGFRA mutated kinases by using a dual mechanism of action that regulates the kinase switch pocket and activation loop. QINLOCK inhibits primary and secondary KIT mutations in exons 9, 11, 13, 14, 17, and 18 involved in GIST, as well as the primary exon 17 D816V mutation. QINLOCK also inhibits primary PDGFRA mutations in exons 12, 14, and 18, including the exon 18 D842V mutation, involved in a subset of GIST.[5,6]

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. 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 the INVICTUS Phase 3 Study

INVICTUS is a Phase 3 randomised, double-blind, placebo-controlled, international, multicenter clinical study evaluating the safety, tolerability, and efficacy of QINLOCK compared to placebo in patients with advanced GIST whose previous therapies have included at least imatinib, sunitinib, and regorafenib. Patients were randomized 2:1 to either 150 mg of QINLOCK once daily (n=85) or placebo (n=44). The primary efficacy endpoint was progression-free survival (PFS) as determined by independent radiologic review using modified Response Evaluation Criteria in Solid Tumors (RECIST). The median PFS in the study was 6.3 months in the QINLOCK arm compared to 1.0 month in the placebo arm and significantly reduced the risk of disease progression or death by 85% (hazard ratio of 0.15, $p<0.0001$) compared to placebo.[1] Secondary endpoints included Objective Response Rate (ORR) as determined by independent radiologic review using modified RECIST and Overall Survival (OS). QINLOCK demonstrated an ORR of 9.4% compared with 0% for placebo ($p=0.0504$), which was not statistically significant.[1] QINLOCK demonstrated a median OS of 15.1 months compared to 6.6 months in the placebo arm and reduced the risk of death by 64% (hazard ratio of 0.36).[1] In a long-term follow up of 19 months after the primary analysis, QINLOCK also demonstrated a median OS of 18.2 months compared to

6.3 months in the placebo arm and reduced the risk of death by 59% (hazard ratio of 0.41).[3] The most common (>2%) grade 3 or 4 treatment related adverse events in the QINLOCK group included lipase increase (5%), hypertension (4%), fatigue (2%), and hypophosphataemia (2%); and in the placebo group, anaemia (7%), fatigue (2%), diarrhoea (2%), decreased appetite (2%), dehydration (2%), hyperkalaemia (2%), acute kidney injury (2%), and pulmonary oedema (2%).[1,4]

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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.

Global Sarcoma Therapy Now Approved for New Zealand Patients

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.

New Therapy to Treat Rare Gastrointestinal Stromal Tumour Approved for New Zealand

Patients

Singapore and New Zealand, 20 January 2023: Independent biopharmaceutical company Specialised Therapeutics Asia (ST) is pleased to announce that a new therapy to treat rare gastrointestinal stromal tumour (GIST) shown to improve survival has now been approved in New Zealand.