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.

Monjuvi® and Minjuvi® are registered trademarks of MorphoSys AG. Tafasitamab is co-marketed by Incyte and MorphoSys under the brand name Monjuvi® in the U.S., and marketed by Incyte under the brand name Minjuvi® in Europe and Canada.

XmAb® is a trademark of Xencor, Inc.

References:

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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]

References

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randomised, placebo-controlled, phase 3 trial. *Lancet Oncol* 2020; 21:923–934.

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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.

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).

International Women's Day 2023

ST Medical Director Paula Fenwick knew from a young age in South Africa that a career in science beckoned. But there were no scientists in her family and her parents were initially reluctant to let her attend university. Her godmother stepped in and helped her blaze a trail that has taken her around the world and allowed her to mentor other young women seeking a STEM career. To mark

#IWD23, Paula reflects on her career journey.

International Women’s Day 2023

Born and raised in cities throughout North India, 28-year-old Prakriti Langer arrived in Australia five years ago to pursue a Masters in Biotechnology. After graduating, “I knew I wanted to gain global exposure. I chose Australia, which is a thriving hub for life sciences.”

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.

Pharma Dispatch: 20 January,

2023

Pharma Dispatch

20 January 2023

New Zealand Approval for Specialised Therapeutics' Cancer Therapy

Specialised Therapeutics Asia has announced that its therapy to treat rare gastrointestinal stromal tumours, QINLOCK (ripretinib), has been approved for use in New Zealand and will now be considered for funding by PHARMAC.

The regulator, Medsafe, has approved QINLOCK for treating adult patients with GIST who have received prior treatment with three or more kinase inhibitors, including imatinib.

The company said it is being made available to eligible patients in New Zealand via a co-pay access program while it is considered by PHARMAC.

In a joint statement, medical oncologists Dr Joanna Connor and Dr Clement Korenbaum from the Auckland City Hospital said QINLOCK would provide patients with another treatment option and align with international standards of care.

"QINLOCK offers clinically meaningful benefits in progression-free and overall survival for patients living with advanced GIST," they said. "It offers an option for patients who have progressed on other treatments."

"We would now support having fully funded access to QINLOCK for all those affected by advanced GIST who meet the pivotal study's criteria."

61-year-old Auckland grandfather and sales manager Tom Turrall was diagnosed with GIST earlier this year after being admitted to hospital for what doctors initially believed was a bleeding ulcer.

“The approval of QINLOCK means hope and an opportunity,” said Mr Turrall.

“I want to live to see my grandchildren grow. I want to live to be able to experience growing old with my wife. I want to live to be able to spend some time relaxing and enjoying what we have worked for. The approval of QINLOCK will remove a level of anxiety that I live with every day as it provides an opportunity for an additional treatment option.”

Mr Turrall said it was critical that PHARMAC now fund QINLOCK.

“PHARMAC funding will mean the financial burden is eased. We consider ourselves the average Kiwi couple. We have worked hard for what we have accumulated and are looking forward to retirement. We are not sure what we will do if we have to fund (any) treatment ourselves.”

QINLOCK belongs to a class of drugs known as tyrosine kinase inhibitors, or TKIs. It is designed to inhibit key enzymes linked to tumour growth. In Australia, it has been fully reimbursed via the PBS since 2021.

Specialised Therapeutics is commercialising QINLOCK in New Zealand under an exclusive distribution agreement from US-based Deciphera Pharmaceuticals.

CEO Carlo Montagner said, “We are hopeful for a positive outcome by PHARMAC so that patients with advanced GIST in New Zealand have ready access to this important new treatment option.”

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.