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

- *QINLOCK® (ripretinib) now Medsafe approved for GIST patients in NZ*
- *QINLOCK now being considered by PHARMAC for reimbursement*
- *Data from the INVICTUS Phase 3 study shows QINLOCK reduces risk of disease progression or death by 85%[1, 2]*

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.

The therapy, QINLOCK® (ripretinib) has been approved for use by the country's regulatory agency Medsafe for the treatment of adult patients with GIST who have received prior treatment with three or more kinase inhibitors, including imatinib.

It is currently being made available to eligible patients in New Zealand via a co-pay Access Program while it is considered by PHARMAC for reimbursement.

Cancer specialists said the approval was welcome news for NZ patients diagnosed with GIST.

In a joint statement, medical oncologists Dr Joanna Connor and Dr Clement Korenbaum from the Auckland City Hospital said QINLOCK would provide patients with more treatment options, aligning with international standard of care.

"QINLOCK offers clinically meaningful benefits in progression free and overall

survival for patients living with advanced GIST," they noted. "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," Mr Turrall said.

"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 funded QINLOCK for patients to ensure all those who are eligible for treatment can afford the therapy.

"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 on the Pharmaceutical Benefits Scheme since 2021.

A pivotal Phase 3 clinical trial of QINLOCK in patients with advanced GIST – 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 (PFS) of 6.3 months in patients administered QINLOCK, compared to 1.0 month in the placebo arm.[1] In addition, in a long-term follow up analysis, patients in the QINLOCK arm demonstrated a median overall survival (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).[1, 4]

QINLOCK is made available in New Zealand by independent pharmaceutical company Specialised Therapeutics (ST) under an exclusive distribution agreement from US based Deciphera Pharmaceuticals.

ST Chief Executive Officer Carlo Montagner said QINLOCK was currently under review by PHARMAC.

“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.”

Ends.

About GIST

Gastrointestinal stromal tumor (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. The risk of GIST diagnosis increases with age, with GIST incidence peaking among people in their fifties and sixties.[5]

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.[6,7] QINLOCK also inhibits primary PDGFRA mutations in exons 12, 14, and 18, including the

exon 18 D842V mutation, involved in a subset of GIST.[6,7]

About Specialised Therapeutics

Headquartered in Singapore, Specialised Therapeutics (ST) is an international biopharmaceutical company established to commercialise new therapies and technologies to patients in Australia, New Zealand and across South-East Asia. ST and its regional affiliates collaborate with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life-changing healthcare solutions to patients affected by a range of diseases. Its mission is to provide therapies where there is an unmet need. The company's broad therapeutic portfolio currently includes novel agents in oncology, haematology, neurology, ophthalmology and supportive care. Additional information can be found at www.stbiopharma.com

About the INVICTUS Phase 3 Study

The INVICTUS Phase 3 study was an international, multicenter, randomised, double-blind, placebo-controlled, trial to evaluate the safety, tolerability, and efficacy of QINLOCK compared to placebo in patients with advanced GIST whose previous therapies have included 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 PFS based on disease assessment by blinded independent central review (BICR) using modified Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 criteria. The median PFS in the study was 6.3 months 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 OS. QINLOCK demonstrated an ORR of 9.4% compared with 0% for placebo ($p=0.0504$)[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).[4] The most frequently observed adverse drug reactions (≥25%) in a pooled safety population (n=392) treated with QINLOCK were fatigue, alopecia, nausea, myalgia, constipation, diarrhea, palmar-plantar erythrodysesthesia syndrome (PPES), weight decreased, and vomiting.[1]

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