‘Great Relief’ for Australian Patients with New Therapy to Treat Rare GIST Cancers Listed on PBS

- *QINLOCK® (ripretinib) now PBS listed for Australian patients*
- *QINLOCK is the first new reimbursed therapy to treat advanced GIST in more than a decade*
- *Leading Australian oncologist says the listing will help to “buy patients more time”*
- *Data shows QINLOCK reduces risk of disease progression by 85%*[1, 2]

14 November, 2021: AUSTRALIAN cancer patients who have been diagnosed with rare gastrointestinal stromal tumours – GIST – will now have affordable access to a new therapy shown to improve survival, following its listing on the Pharmaceutical Benefits Scheme (PBS).[3]

The therapy, QINLOCK (ripretinib) is an oral medication and will be available to eligible patients on the PBS from **December 1**, in a listing described by cancer specialists and patient advocacy groups as “a great relief” for patients.

Leading Australian oncologist Professor John Zalcberg, who is a consultant medical oncologist at Alfred Health and is Head of Monash University’s Cancer Research Program in the School of Public Health, welcomed the reimbursement of QINLOCK, describing it as a “fantastic” result for patients and their families.

Professor Zalcberg commented: “It has been more than 10 years since a new therapy able to treat GIST has been listed on the PBS. QINLOCK is a therapy that can buy patients more time, but the market price of this therapy has meant that until now, it has been out of bounds for most people. This PBS listing will be welcomed by many Australian patients and their families.”

35-year-old Melbourne mother of two Renee Van Beelen was diagnosed with GIST five years ago, only eight weeks after giving birth to her second child. She has had her stomach removed and endured several cancer recurrences. She is relieved another therapy is now accessible.

“It can buy me time, at a price that we can afford for our family,” she said. “We simply would not have been able to come up with thousands of dollars every month. Having QINLOCK listed on the PBS means the world to us, because it means I have another tool in my back pocket to help me watch my children grow up. All I want is to create moments with my family and knowing that this therapy is available on the PBS is a huge relief.”

And Canberra teacher and mother Sarah McGoram, who was given a year to live 25 years ago, says this listing “will have a profound impact on my family.”

Sarah, who has led a national lobby campaign fighting for QINLOCK to be funded, says: “QINLOCK being funded on the PBS can buy me time. It buys me a treatment option that was not otherwise there. That’s all I want. I just want time with my family and time to fight this frustrating disease.”

Rare Cancers Australia Chief Executive Officer Richard Vines said today was “a red-letter day” for the GIST community, as patients previously had no further treatment options after other therapies failed.

“QINLOCK offers hope, it offers time and it offers a future that otherwise they would not have had,” Mr Vines said. “This has been a long time coming for GIST patients and it is a fantastic result.”

QINLOCK belongs to a class of drugs known as tyrosine kinase inhibitors, or TKIs. It works by inhibiting key enzymes linked to tumour growth. It is now reimbursed “**for the treatment of patients with advanced metastatic or unresectable GIST who have progressed following treatment with imatinib and sunitinib.**” [3]

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] In addition, in a long-term follow up analysis, patients in the QINLOCK arm achieved a median overall survival of 18.2 months compared to 6.3 months in the placebo arm and QINLOCK reduced the risk of death by 58% (hazard ratio of 0.42).[1, 4]

QINLOCK is made available in Australia by independent pharmaceutical company Specialised Therapeutics (ST) under exclusive license from US based Deciphera Pharmaceuticals.

ST Chief Executive Officer Carlo Montagner said it was vital rare cancer patients were provided affordable access to specialist medicines.

“Without PBS reimbursement, most patients would be unable to afford this therapy,” he said. “We are celebrating the PBS listing of QINLOCK and look forward to seeing it make a difference to GIST patients and their families.”

VNR Includes:

- Interview and overlay: Leading Australian oncologist, Professor John Zalcberg, who says this is “a great relief” for GIST patients and their families. Professor Zalcberg is available for further interview by emailing john.zalcberg@monash.edu
- Interview and overlay with 35-year-old mother of two Renee Van Beelen, who says the PBS listing of QINLOCK “will buy me more time”. She is based in Melbourne and is available for further interview on **0403 204 863.**
- Interview and overlay with Canberra teacher, mother and rare cancer access lobbyist Sarah McGoram, who was diagnosed with GIST 25 years ago and given 12 months to live. She is available for further interview on **0415 720 928.**
- Overlay QINLOCK pack shots
- QINLOCK mechanism of action video
- Interview and overlay Rare Cancers Australia CEO Richard Vines, who outlines what the PBS listing of QINLOCK means for patients and why other medicines for rare cancer patients should be accessible via the PBS.

Further Interviews Available:

Western Australia: 51-year-old father of four and Curtin University academic Nigel Marks was diagnosed with GIST six years ago, when his youngest child was just 10. He says he "burst into tears" when the PBS listing of QINLOCK was announced, after lobbying WA MPs. "This is pushing the future further into the future. The more options the better." He is available for further interview on **0402 379 209 or 08 92661386.**

Queensland: 54-year-old mother and army base canteen manager Jacqui Bartlett was diagnosed with GIST in 2016 and her cancer has recurred. She is now living with multiple tumours, and says she is "absolutely stoked" at the PBS listing of QINLOCK. "It will give me a chance to keep working and pay off my mortgage and have something for my son. It is a sense of relief that there is now something else that will prolong my life, basically. And something that I can afford." Jacqui is available for further interview on **0412 727 353.**

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 GISTs are 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 in Australia. 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 PDGFRα mutated kinases by using a dual mechanism of action that regulates the kinase switch pocket and activation loop to lock the kinase in the inactive state, preventing downstream signalling and cell proliferation. This dual mechanism of action provides broad inhibition of KIT and PDGFRA kinase activity, including wild type and multiple primary and secondary

mutations. Ripretinib also inhibits other kinases in vitro, such as PDGFRB, TIE2, VEGFR2, and BRAF.[2]

About Specialised Therapeutics

Headquartered in Singapore, Specialised Therapeutics Asia Pte Ltd (STA) is an international biopharmaceutical company established to commercialise new therapies and technologies to patients throughout South East Asia, as well as in Australia and New Zealand. STA 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

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 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 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, $p<0.0001$).[1] Secondary endpoints as determined by independent radiologic review using modified RECIST included Objective Response Rate (ORR) and Overall Survival (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 58% (hazard ratio of 0.42).[4] 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]

Further Enquiries

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References:

1. Blay J-Y et al. Ripretinib in patients with advanced gastrointestinal stromal tumours (INVICTUS): a double-blind, randomised, placebo-controlled, phase 3 trial. *Lancet Oncol.*2020; 21: 923-934
2. QINLOCK (ripretinib) TGA approved Product Information
3. QINLOCK (ripretinib) PBS Listing https://www.pbs.gov.au/browse/medicine-listing
4. Von Mehren M et.al. Presented at ESMO 2021 virtual meeting, 16-21 September 2021
5. GI Cancer Institute Australia https://gicancer.org.au/cancer/gastro-intestinal-stromal-tumour-gist/#cancer-explanation

MINIMUM PRODUCT INFORMATION

QINLOCK™ (ripretinib) 50 mg tablets

Indications: QINLOCK is a kinase inhibitor indicated 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.

Contraindications: Hypersensitivity to ripretinib, or to the excipients. QINLOCK contains lactose.

Precautions: Palmar-plantar erythrodysaesthesia syndrome (PPES); New primary cutaneous malignancies including cutaneous squamous cell carcinoma, keratoacanthoma and melanoma; hypertension; cardiac dysfunction including cardiac failure, acute left ventricular failure, diastolic dysfunction, ventricular hypertrophy and decreased ejection function. Fertile females and males must use effective contraception during treatment and for at least 1 week after the final dose.

Interactions: Co-administration with strong CYP3A inhibitors (e.g. itraconazole) and inducers should be avoided since they are expected affect the plasma concentration of QINLOCK and its active metabolite. Co-administration with P-gp inhibitors may increase plasma concentrations of QINLOCK and its active metabolite therefore caution should be taken. QINLOCK is expected to increase clinical exposures of other medications that are predominantly cleared by CYP2C8.

Adverse Reactions: Most common: alopecia, fatigue, nausea, abdominal pain, constipation, myalgia, diarrhoea, decreased appetite, PPES and laboratory abnormalities (increased lipase and decreased phosphate).

Dose and method of administration: The recommended dose of QINLOCK is 150 mg (three 50 mg tablets) taken orally once daily with or without food. Refer to full PI for management of dose adjustments and more information.

Date of First Approval: 13 July 2020

Please review Product Information before prescribing. The Product Information can be accessed at www.ebs.tga.gov.au.

To report any adverse events, please contact: drugsafety-sta@stbiopharma.com

PBS Information: Authority required
Refer to PBS Schedule for full authority information