New Drug for Gastrointestinal Stromal Tumours (GIST) to be Launched in Australia, New Zealand and South East Asia Following Distribution Agreement

Singapore, 06 November 2020: A NEW therapy to treat advanced gastrointestinal stromal tumours (GIST) will be available to patients in Australia, New Zealand and in some parts of South East Asia, following an exclusive distribution agreement.

Independent pharmaceutical company Specialised Therapeutics Asia (STA) has signed an agreement with US-based Deciphera Pharmaceuticals, Inc. (NASDAQ: DCPH) to commercialise the switch-control tyrosine kinase inhibitor QINLOCK (ripretinib) in key regions, including Australia, New Zealand, Singapore, Malaysia and Brunei.

The therapy was one of the first approved by Australia's Therapeutic Goods Administration (TGA) earlier this year under Project Orbis, which enables concurrent review of oncology products by international regulators, including the TGA, FDA and Health Canada.

It is indicated **"for the treatment of adult patients with advanced gastrointestinal stromal tumours (GIST) who have received prior treatment with three or more kinase inhibitors, including imatinib"**.

QINLOCK has also been approved by the US Food and Drug Administration (FDA) and Health Canada (HC) for the fourth-line treatment of GIST.

The TGA approval was based on efficacy results from the pivotal global Phase 3 INVICTUS study in patients with advanced GIST as well as combined safety results from INVICTUS and the Phase 1 study of QINLOCK. In INVICTUS, QINLOCK demonstrated a median progression-free survival of 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; 95% CI 0.09-0.25; p<0.0001). In addition, QINLOCK demonstrated a median overall survival 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; 95% CI 0.21-0.62).[1]

One of the INVICTUS study authors, Professor John Zalcberg who holds the Tony Charlton Chair of Oncology and is Head of the Cancer Research Program in the School of Public Health at Monash University as well as a consultant medical oncologist at Alfred Health, described QINLOCK as an important new agent in the GIST treatment armamentarium, noting it was the first TGA approved fourth-line therapy to treat the disease.

“QINLOCK represents another step forward to improve outcomes for patients who are affected by this rare cancer,” Professor Zalcberg said.

“This is an area of high unmet need because of the poor prognosis of patients whose tumours continue to grow on prior treatment.

“We are further encouraged by data demonstrating that QINLOCK is well-tolerated, with patient-reported outcomes (PROs) suggesting that patients who received QINLOCK therapy in the INVICTUS study were able to maintain their quality of life in contrast to the fact that quality of life deteriorated in patients not receiving QINLOCK.”

STA Chief Executive Officer Carlo Montagner said QINLOCK would bolster the company’s already-robust oncology portfolio, and was synergistic with its mission to address areas of unmet clinical need.

“We are thrilled to introduce this valuable therapy to patients with GIST in our region, working in collaboration with our new international partner, Deciphera Pharmaceuticals,” Mr Montagner said.

“STA will expedite access to this important medicine, with a Patient Access Program to open in Q1 2021. This will provide subsidised access for appropriate patients at the earliest opportunity, as we file for additional regulatory approvals in other key markets, including New Zealand, Singapore and Malaysia.”

Deciphera President and Chief Executive Officer Mr Steve Hoerter commented: “We are committed to ensuring QINLOCK’s global commercial availability and are

proud to be executing on our plan to deliver this important medicine to patients with advanced GIST worldwide.

“We look forward to collaborating with STA as we bring a much-needed therapeutic option to patients living in locations where we do not anticipate setting up our own commercial activities near term.”

A submission to have QINLOCK reimbursed for eligible Australian patients has been lodged with the Pharmaceutical Benefits Advisory Committee in November for consideration at the March 2021 meeting. If successful, QINLOCK could be reimbursed for Australian patients in the latter half of 2021.

Ends.

Further inquiries: STA Senior Manager Communications and Corporate Affairs Emma Power +61 419 149 525.

About Specialised Therapeutics Asia

Specialised Therapeutics Asia Pte Ltd (ST Asia) is an international biopharmaceutical company established to provide pioneering healthcare solutions to patients throughout South East Asia, as well as in Australia and New Zealand.

ST Asia 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. ST Asia is committed to making new and novel therapies available to patients around the world targeting diseases where there remain unmet medical needs. STA’s broad therapeutic portfolio currently includes novel agents in oncology, haematology, neurology, ophthalmology and supportive care.

Additional information can be found at www.STAbiopharma.com

About Deciphera Pharmaceuticals

Deciphera is a biopharmaceutical company focused on discovering, developing and commercializing important new medicines to improve the lives of people with cancer. Deciphera is leveraging its proprietary switch-control kinase inhibitor platform and deep expertise in kinase biology to develop a broad portfolio of innovative medicines. In addition to advancing multiple product candidates from the company's platform in clinical studies, QINLOCK is Deciphera's FDA-approved switch-control kinase inhibitor for the treatment of fourth-line gastrointestinal stromal tumor (GIST). QINLOCK is also approved for fourth-line GIST in Canada and Australia. For more information, visit www.deciphera.com and follow the company on LinkedIn and Twitter (@Deciphera).

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 is the most common sarcoma of the gastrointestinal tract, with approximately 4,000 to 6,000 new GIST cases each year in the United States and a similar incidence rate in European and other countries. Most cases of GIST are driven by a spectrum of mutations. The most common primary mutations are in KIT kinase, representing approximately 80% of cases, or in PDGFRα kinase, representing approximately 6% of cases. Current therapies are unable to inhibit the full spectrum of primary and secondary mutations, which drives resistance and disease progression. Estimates for 5-year survival range from 48% to 90%, depending on the stage of the disease at diagnosis.

About the INVICTUS Phase 3 Study

INVICTUS is a Phase 3 randomized, 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 or placebo once daily. The primary efficacy endpoint is 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, $p<0.0001$). Secondary endpoints as determined by independent radiologic review using modified RECIST include Objective Response Rate (ORR) and Overall Survival (OS). QINLOCK demonstrated an ORR of 9.4% compared with 0% for placebo ($p=0.0504$). QINLOCK also 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).

About QINLOCK (ripretinib)Specialised

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. 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 involved in systemic mastocytosis, or SM. QINLOCK also inhibits primary PDGFRα mutations in exons 12, 14, and 18, including the exon 18 D842V mutation, involved in a subset of GIST.

QINLOCK is approved by the U.S. FDA for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. It is also approved by Health Canada for the treatment of adult patients with advanced GIST who have received prior treatment with imatinib, sunitinib, and regorafenib and by the Australian Therapeutic Goods Administration for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib.

Deciphera Pharmaceuticals is developing QINLOCK for the treatment of KIT

and/or PDGFRα-driven cancers, including GIST, and maintains global development and commercial rights except for select geographies. Deciphera Pharmaceuticals has an exclusive license agreement with Zai Lab (Shanghai) Co., Ltd. for the development and commercialization of QINLOCK in Greater China (Mainland China, Hong Kong, Macau, and Taiwan). Deciphera Pharmaceuticals has an exclusive distribution agreement with Specialised Therapeutics Asia (STA) for the commercialization of QINLOCK in Australia, New Zealand, Singapore, Malaysia and Brunei.

- • Specialised Therapeutics Asia (STA) to make QINLOCK® (ripretinib) available to appropriate patients in Australia, New Zealand, Singapore, Malaysia and Brunei following exclusive distribution agreement
- • QINLOCK is already approved by the Therapeutics Good Administration (TGA) and US Food and Drug Administration (FDA)
- • In the INVICTUS study, QINLOCK reduced the risk of disease progression by 85% in advanced GIST patients who have received three prior therapies[1]

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