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PHARMADISPATCH

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Australians Will Need to 'Reconcile Themselves to this New Reality'

November 6, 2020 — Privately owned Australian pharmaceutical company Specialised Therapeutics Asia has signed an exclusive distribution agreement for a new therapy to treat advanced gastrointestinal stromal tumours (GIST).

The agreement with US-based Deciphera Pharmaceuticals covers the commercialisation of switch-control tyrosine kinase inhibitor QINLOCK (ripretinib) in a number of countries, including Australia, New Zealand, Singapore, Malaysia and Brunei.

The therapy, which was approved by the TGA earlier this year, was considered under Project Orbis. The project enables the concurrent review of oncology products by international regulators, including the TGA, FDA and Health Canada.

QINLOCK was approved in Australia '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'.

The approval was based on efficacy results from the pivotal global phase three INVICTUS study in patients with advanced GIST. It was also based on combined safety results from INVICTUS and a phase one study.

In INVICTUS, QINLOCK demonstrated a median progression-free survival of 6.3 months compared to 1 month in the placebo arm and significantly reduced the risk of disease progression or death by 85 per cent.

QINLOCK also 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 per cent.

One of the INVICTUS study authors, Professor John Zalcberg, described QINLOCK as an important new agent for the treatment of GIST, saying 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,” said Professor Zalcberg.

“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 CEO Carlo Montagner said QINLOCK would bolster the company’s 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,” said 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.”

STA said the Pharmaceutical Benefits Advisory Committee will consider QINLOCK for the PBS at its March 2021 meeting.

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.

Deciphera president and CEO Mr Steve Hoerter added, “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.”