Pharma in Focus: 15 March, 2021

PHARMA IN FOCUS

By Nick Lush 15 March 2021

Is This a Funding Breakthrough?

With the Zimmerman inquiry being told the PBAC is not up to scratch on delivering medicines to Australian patients, a 'thinking outside the square' option being pioneered by local pharmaSpecialised Therapeutics (STA) appears to be blazing a new funding trail.

STA has today announced that, after "six frustrating attempts" to secure government reimbursement for a cancer diagnostic without success, it has won backing from the private sector that will support patients financially while it continues to seek public funding.

The company has struck an agreement with Latitude Finance so breast cancer patients can access the Oncotype DX test, "which has been shown in large randomised clinical studies published in leading medical journals to identify the majority of breast cancer patients who do not benefit from chemotherapy".

"Under the terms of the new agreement, Australian women who decide to take an Oncotype DX Breast Recurrence Score test can now use an interest-free two-year payment plan to help afford the $5000 one-off test," STA said.

"We have tried on multiple occasions to have this test reimbursed for Australian women. These efforts are ongoing, but we trust that in the interim, this new third-party finance arrangement will help many breast cancer patients afford this important technology which in turn, may help them to avoid chemotherapy," STA CEO Carlo Montagner said.

"As a company and a community, we must find new ways for all Australians to access new therapies and technologies that are recommended by their specialist doctors but are not reimbursed.

This is a step in the right direction. STA is proud to partner with Latitude Finance, which has an established presence in healthcare and is now extending its offering in this space due to strong patient demand," Montagner added.

The Oncotype DX test is marketed in Australia by STA under exclusive license from US-based Exact Sciences and is appropriate for women who have been diagnosed with early breast cancer, whose cancer is hormone receptor positive, HER2 negative and has up to three positive lymph nodes, STA said.

"Without federal government funding and without accessible personal savings, hundreds of Australian women have been unable to afford this important test," Montagner said.

Interest-free payment plans to access the Oncotype DX Breast Cancer Recurrence Score Test become available from today, STA said.

Channel 10 News: December 2020

The following stories appeared on Channel 10 News and other news outlets nationally. Click on the thumbnails below to view them.

Breast Surgeon Dr Jane O’Brien on Channel 10 News

Breast Cancer Surgeon Dr Chantel Thornton on ABC News

Breast Cancer Surgeon Dr Chantel Thornton on 7 News

Breast Surgeon Dr Jane O’Brien on Channel 7 News

EOC Award: CEO Comment

Watch Video

Click on the video banner above to watch CEO Carlo Montagner discuss STA's 2020 Employer of Choice award on Ticker News.

For more information visit https://employerofchoiceawards.com.au/eoc-winners-2020/specialised-therapeutics-2020-eoc/

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EOC EMPLOYER OF CHOICE WINNER 2020

Pharma Dispatch: 6 November, 2020

PHARMADISPATCH

6 November 2020

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.”

STA Announces New US Partner

PHARMADISPATCH

6 November 2020

Australian Company Adds to its Oncology Portfolio with GIST Therapy

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Biospace: 16 July, 2020

BIOSPACE

16 July 2020

New Early Breast Cancer Drug Now Approved in Malaysia

SINGAPORE, July 16, 2020 /PRNewswire/ — A NEW breast cancer drug shown to significantly reduce the risk of cancer recurrence is now approved for use in

Malaysia.

The drug, NERLYNX (neratinib), is an oral medication taken by women with breast cancer who have had surgery, chemotherapy and prior trastuzumab-based therapy.

It has been shown to significantly reduce the ongoing risk of recurrence in HER2+ early breast cancer patients,[2] with the greatest benefit seen in women who are also hormone-receptor positive (HR+) and who commence therapy within 12 months of completing trastuzumab-based therapy. For these women, the five-year risk of recurrence is reduced by up to 42%.[1]

NERLYNX is approved in Malaysia for "the extended adjuvant treatment of women with early-stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who completed adjuvant trastuzumab-based therapy less than one year ago."

Nerlynx was also recently approved in Singapore by the HSA.

Independent pharmaceutical company, Specialised Therapeutics Asia (STA) is making NERLYNX available in South East Asia under exclusive license from Puma Biotechnology Inc.

STA Chief Executive Officer Mr Carlo Montagner said the latest approval in Malaysia represented a key commercial milestone and highlighted the company's expertise in navigating regulatory pathways in these complex regions.

"Our regulatory team has worked tirelessly to secure these approvals for NERLYNX in Singapore and now Malaysia," he commented.

"NERLYNX is the first drug in our portfolio to be approved in these regions. We are now rapidly progressing other portfolio products through relevant regulatory channels to enable patients across South East Asia access to therapies where there is an unmet medical need.

"In the case of NERLYNX, we look forward to seeing women throughout South East Asia benefit from this important therapy, that provides an opportunity to improve outcomes for early breast cancer patients."

Professor Arlene Chan was the lead investigator and primary author in the pivotal Phase 3 trial of NERLYNX, ExteNET.[2]

Professor Chan said its availability in Malaysia, as well as Singapore, would be "a huge step forward" to further reduce the risk of cancer recurrence in local women diagnosed with HER2+ early breast cancer.

"Despite the clear proven benefit of standard of care chemotherapy and trastuzumab therapy, women diagnosed with early-stage HER2+ breast cancer are still at risk of disease recurrence," Professor Chan said.

"This drug provides women with an opportunity to remain disease-free who may otherwise have had a recurrence."

Data from the Malaysia National Cancer Registry Report (MNCRR) 2012-2016 demonstrates that the number of breast cancer cases being recorded in Malaysia is rising, with around 34 women in every 100,000 diagnosed with the disease between 2012 to 2016, compared to about 31 women between 2007 to 2011.[3]

Singapore health data shows that breast cancer is the most common cancer in women in the country, accounting for almost 30% of all cancer cases. It is estimated that one in 15 women will be diagnosed with breast cancer before age 75.[4]

About NERLYNX[5]

NERLYNX (neratinib) is an irreversible tyrosine kinase inhibitor that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER4.

NERLYNX is the first HER2-targeted medication approved by the Australian TGA, the US Food and Drug Administration (FDA)[4] and the European Medicines Agency (EMA)[6] as extended adjuvant treatment for early-stage HER2-positive (HER2+) breast cancer, for patients who have previously been treated with trastuzumab following surgery (i.e., adjuvant trastuzumab-based therapy).

Extended adjuvant therapy is the next step of treatment that follows adjuvant

therapy (treatment after surgery) to further reduce the risk of breast cancer returning.

NERLYNX is an oral tablet and works by binding to multiple receptors inside the cancer cell, blocking signals that tell cancer cells to grow and multiply.

About HER2+ Breast Cancer

Up to 20% of patients with breast cancer tumors over-express the HER2 protein (HER2-positive disease) and in the ExteNET study, 57% of patients were found to have tumors that were hormone-receptor positive. HER2-positive breast cancer is often more aggressive than other types of breast cancer, increasing the risk of disease progression and death. Although research has shown that trastuzumab can reduce the risk of early stage HER2-positive breast cancer recurring, up to 25%[7] of patients treated with trastuzumab experience recurrence within 10 years, the majority of which are metastatic recurrences.

About the ExteNET Study[2,8]

The ExteNET trial was a double-blind, placebo-controlled, Phase III trial of neratinib versus placebo after adjuvant treatment with trastuzumab (Herceptin) in patients with early-stage HER2-positive breast cancer.

The ExteNET trial randomised 2,840 patients in 41 countries with early-stage HER2-positive breast cancer who had undergone surgery and adjuvant treatment with trastuzumab. After completion of adjuvant treatment with trastuzumab, patients were randomised to receive neratinib or placebo for a period of one year. Patients were then followed for recurrent disease, ductal carcinoma in situ (DCIS), or death for a period of five years after randomisation.

The primary endpoint of the trial was invasive disease free survival (iDFS). The trial demonstrated that after a median follow up of 5.2 years, treatment with neratinib resulted in a 27% reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.73, p = 0.008). The 5-year iDFS rate for the neratinib arm was 90.2% and the 5-year iDFS rate for the placebo arm was 87.7%.[8]

An additional five-year sub-group analysis demonstrated a 42% risk reduction in women who were HR+ and who had commenced neratinib therapy within 12 months of completing treatment with trastuzumab.[8]

Puma is conducting a Phase 2 CONTROL study investigating various prophylactic anti-diarrhoeal regimens for the first 1-2 cycles of neratinib therapy. Emerging data suggest that prophylactic management reduces the incidence, severity and duration of neratinib-associated diarrhoea as compared with events observed in ExteNET.

About Specialised Therapeutics Asia

Headquartered in Singapore, Specialised Therapeutics Asia Pte Ltd (STA) is an international biopharmaceutical company established to 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

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Cision View original content:http://www.prnewswire.com/news-releases/new-early-breast-cancer-drug-now-approved-in-malaysia-301095220.html

SOURCE Specialised Therapeutics Asia

Pharma in Focus: 16 April, 2020

PHARMA IN FOCUS

By Megan Brodie 16 April 2020

PBAC fees too high for little guy

The owner of Australia's largest independent pharmaceutical company says changes to PBAC fees mean small companies need to budget almost $2 million to make a submission for a medicine to be listed on the PBS, with no guarantee of success.

In a submission on new fees being introduced as part of PBS process improvements, Specialised Therapeutics Australia CEO Carlo Montagner said the proposed fee hikes due to take effect on 1 July presented "a major barrier" to PBS access for small, independent pharma companies like STA.

"These fee increases will mean the cost of submitting a major submission is now well in excess of $300,000 – irrespective of whether the application is successful," Montagner said.

"STA has estimated that the combination of fee increases, new fees for various processes and internal costs of submission preparation will mean that the real

cost per submission is approaching $750,000.

“Considering that it typically takes several submissions to achieve a PBS listing, companies need to budget almost $2 million for a
single submission, with no predictability that the submission will be successful or commercially feasible if onerous listing conditions are mandated by the PBAC.”

Montagner argues large, multinational companies are more able to bear the upfront cost of larger fees while for smaller companies, they “potentially mean the financial risk is simply too great, especially when the outcome of a PBAC submission is highly unpredictable”.

The STA submission proposes companies like STA with annual revenues of less than $50 million be granted an exemption from paying new fees ‘upfront’ for at least the first two PBAC applications, instead paying back the cost in instalments after a successful PBS listing and earnings of more than $3 million a year.

Montagner says STA’s experience was that demonstrating statistically significantly improved survival data and furnishing positive funding recommendations from key overseas agencies did not guarantee success at PBAC.

In the past year, STA has twice submitted unsuccessfully for breast cancer drug Nerlynx and also twice for myeloma therapy Aplidin at a combined fee cost of almost $1 million. The outcome of its second Aplidin submission will be released next week.

He said the proposed fee hikes, such as the $238,230 fee for the facilitated resolution pathway and the $72,000 cost of an associated facilitated workshop, “appear exorbitant”and “seem disproportionate to the work input required by the Department of Health”.

STA supported a call by Medicines Australia for an independent audit of the proposed charges, with Montagner saying “more clarity is required”.

Montagner says while “there will always be risk when it comes to bringing new medicines to market”, “the reality is that with the new fees and increases to existing fees, pharmaceutical companies will be spending in excess of $3 million for every drug they try to list”.

“It’s a vast amount of money when there is no definitive predictor of listing

success that a company can rely on to determine the degree of investment risk."

Orphan drugs hardest hit

Montagner says orphan drug submissions will be particularly adversely impacted by the proposed fee hikes as their potential PBS revenue is insufficient to justify the multi-million dollar outlay required to submit them to the PBAC.

"I would like to propose that the first two PBAC submissions for orphan designated drugs are fee exempt, with a further minor submission included (if this is required following an unsuccessful second major submission)," he says.

Montagner says when the full impact of the July 2020 PBAC fee increases is realised in two to three years, small Australian-owned companies like STA "will not be able to take on the financial burden and associated risk to bring these new medicines to Australia".

"Ultimately, this means that patients will miss out, because the international drug development companies STA partners with to make these therapies available do not have an established presence in this region.

"Of most concern is that Australia will end up like New Zealand, where many companies no longer submit products for regulatory approval due to the low probability of achieving reimbursement."

Pharma Dispatch: 16 April, 2020

Pharma Dispatch

16 April 2020

STA: New fees a “major barrier” to patient access

Specialised Therapeutics Australia says proposed further increases in PBS submission and listing fees are “prohibitive” for smaller companies and risk becoming a “major barrier” to patient access to new medicines.

The Department of Health recently announced new and higher cost recovery fees for new vaccines and medicines that will be implemented from mid-2020. They build on the range of fee changes implemented from mid-2019.

Specialised Therapeutics Australia (STA) is a privately owned pharmaceutical company led by Carlo Montagner.

“Our mission has always been to fulfil unmet medical needs – we do not in-license ‘me-too’ therapies where there is a comparable competitor already in the market,” said the company in its submission on the proposed fees.

“All products in our portfolio are carefully and prudently selected for the incremental clinical benefit they provide, particularly to smaller patient populations. Typically, we partner with smaller European or USbased biotech companies that do not have a presence in our region. Therefore, if STA did not partner
with these companies, their products would not be available to patients in Australia,” it said.

The company said it backs the concerns raised by Medicines Australia.

“These fee increases will mean the cost of submitting a major submission is now well in excess of $300,000 – irrespective of whether the application is successful,” it said.

“STA has estimated that the combination of fee increases, new fees for various processes and internal costs of submission preparation will mean that the real

cost per submission is approaching $750,000.

“Considering that it typically takes several submissions to achieve a PBS listing, companies need to budget almost $2 million for a single submission, with no predictability that the submission will be successful or commercially feasible, if onerous listing conditions are mandated by the PBAC.”

It said the cost of making a submission is “increasingly prohibitive” but that they present a “major barrier” for independent and privately-owned companies like STA.

“While these commercial considerations are matters for all pharmaceutical companies, larger multinational companies have far greater financial resources to bear this cost upfront,” it said.

It continued, “For smaller companies in this industry with a turnover of less than $50 million annually, these increased costs will potentially mean the financial risk is simply too great, especially when the outcome of a PBAC submission is highly unpredictable.”

The company highlighted its “own experience with recent major submissions” where it said high-level of evidence and improved outcomes for patients had still resulted in rejections.

It pointed to its submissions on breast cancer therapy NERLYNX (neratinib) and myeloma therapy APLIDIN (plitidepsin).

“Even based on the older fee structure and levels, these four applications have cost our company almost $1 million in fees,” it said, adding the new fee structure means pharmaceutical companies will be spending in excess of $3 million for every medicine they try to list on the PBS.

STA backed an independent audit of the changes and proposed special consideration for companies with annual revenues of less than $50 million.

“I am respectfully requesting that smaller companies with revenue <$50M annually be granted an exemption from paying new fees ‘upfront’ for at least the first two applications, and when, or if, a drug is listed on the PBS, the company then pays those fees in arrears, in instalments when PBS expense on that drug exceeds $3M per year.”

On orphan drugs, STA said, “While the PBAC provides an exemption on the initial PBAC submission for drugs that have been orphan-designated, this is not the case for subsequent submissions.

“As stated earlier, it typically takes two to three submissions for a drug to receive a positive PBAC approval.

“Given this statistic, we are now faced with a real barrier for orphan drugs to be PBS listed as the likelihood of success in the only fee exempt round (first submission) is low, and the revenue that would be generated by the orphan drug insufficient to justify the multi-million dollar outlay required for subsequent submissions.”

The company proposed that the first two PBAC submissions for orphan designated drugs should be fee exempt with a further minor submission included.

The Courier Mail: 22 February, 2020

THE COURIER MAIL

By Sue Dunlevy 22 February 2020

Breast cancer test fail

Government denies funding to help avoid chemo

A $5000 test that can indicate whether a breast-cancer patient needs

chemotherapy has been rejected for a government subsidy even though it could potentially save thousands of women from having to undergo the harrowing cancer treatment.

The Federal Government's Medical Services Advisory Committee said there was not enough evidence to support a Medicare rebate for the test.

But breast cancer support groups are furious with the decision.

And US breast cancer expert Dr Eric Winer, from the Dana-Farber Cancer Institute in Boston, said he was "shocked" by the MSAC decision.

In the US, all insurers paid for the genetic test for women with HER2-positive breast cancer when the cancer had not spread to the patients' lymph nodes, he said

"I think it's a mistake," he said. "To put it simply for a sizeable group of patients the decision tools you have will continue to be from the year 2000, instead of taking advantage of new tools for treatment decision."

The Oncotype DX test analyses 21 genes from a breast tumour and can help predict the risk that a woman's breast cancer may recur, and the likely benefit chemotherapy may have in reducing that risk.

Specialised Therapeutics performs the test in a single laboratory in the US and it has not been approved for use by regulatory authorities such as the US Food and Drug Administration nor by the Australian Therapeutic Goods Administration.

A clinical trial of 10,273 women with breast cancer found nine years after diagnosis the rate of disease-free survival was similar for women with a mid range score in the gene test. Disease-free survival for those who received hormone therapy only was 83 per cent compared with women who received both hormone therapy and chemotherapy (84.3 per cent).

Specialised Therapeutics Australia Pty Ltd had applied for public funding of the Oncotype DX test in Australia but MSAC rejected the application on Thursday night.

A spokeswoman for Breast Cancer Network Australia said they were disappointed the test had been rejected. "We urge the companies supplying these tumour

profiling tests to get together with the Government to find a way forward," BCNA chief executive Kirsten Pilatti said.

The Daily Telegraph: 22 February, 2020

THE DAILY TELEGRAPH

By Sue Dunlevy 22 February 2020

Tussle over cancer test

Rejection angers support group

A $5000 test that can indicate whether a breast cancer patient needs chemotherapy has been rejected for a government subsidy, even though it would mean thousands of women could avoid the harrowing treatment.

The government's Medical Services Advisory Committee said there was not enough evidence to support a Medicare rebate for the test.

Breast cancer support groups are furious with the decision, which has also shocked at least one US expert.

"I think it's a mistake," Boston's Dama Faber Institute expert Dr Eric Winer said. In the US, all insurers paid for the genetic test for women with HER2-positive breast cancer when the cancer had not spread to the patient's lymph nodes, he said.

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Specialised Therapeutics Australia Pty Ltd applied for had public funding of the Oncotype DX test in Australia but was rejected this week.

MSAC advised that the evidence "did not give the committee confidence that the test would identify those patients who could safely avoid chemotherapy".

Breast Cancer Network Australia was disappointed the test had been rejected. "If we can identify those people who will benefit from not having chemotherapy, it is essential that we save them from over-treatment," CEO Kirsten Pilatti said, adding chemotherapy has significant long-term impacts on patients' health.

Kari Svensen (pictured) was able to afford the genetic test when diagnosed with breast cancer five years ago. The now 73-year-old from St Ives said it found she didn't need chemotherapy and instead she underwent radiation treatment — and is still cancer-free.

"I fervently wish this test was available to all Australian women," she said.