

The Australian: 6 April, 2018

The Australian

By Sarah-Jane Tasker 6 April 2018

New Breast Cancer Drug Reduces Risk of Relapse

Australians with breast cancer can apply to receive a drug that reduces the risk of cancer returning, under a special access program.

Nerlynx is targeted for use in women with HER 2+ early breast cancer. One in four women diagnosed with this type of cancer can suffer a relapse in five years and it is believed that taking Nerlynx will prevent some of those recurrences.

The drug's marketer in Australia, Specialised Therapeutics, is seeking regulatory approval of the drug for it to be reimbursed by the government and has launched the special access program while it awaits regulatory approval.

Under the program, select patients in Australia would be provided access to the medicine, where appropriate and when permitted by relevant regulatory authorities. In all cases, the patient must have a special clinical need that cannot be met by currently approved and available medicines.

Principal trial investigator of the drug, Arlene Chan, has previously highlighted that the availability of Nerlynx in Australia and other regions was an important step in reducing recurrence in HER 2+ early breast cancer.

"My hope and expectation is that with longer follow-up, not only will recurrence rates be reduced, but they will show that the use of Nerlynx will improve overall survival," the world renowned Perth oncologist said.

Herald Sun: 5 October, 2017

The Australian

By Sue Dunlevy 5 October 2017

Test rebate rejected: Outrage over breast cancer ruling

NO Medicare rebate will be offered for a breakthrough new test that could save thousands of breast cancer patients from debilitating chemotherapy.

The \$4500 test, which can also identify aggressive breast cancers that do need chemotherapy, is subsidised in the United Kingdom, the United States, Canada and Europe. But the Medical Services Advisory Committee has rejected a rebate for the Oncotype DX test for a fifth time.

Critics say the best treatment will now be available only to the rich. Doctors fear low-income earners will never even be offered the test.

“It’s beyond belief they can be so hard-hearted — they must be a bunch of men,” said Kari Svensen, 71, of Sydney, who was able to avoid chemotherapy thanks to the test.

Wendy Dunstone, of Melbourne, was not going to have chemotherapy until the test showed her cancer was an aggressive type. She was only able to afford the test thanks to an inheritance.

Explaining its decision, the MSAC said the test had only an incremental benefit over the usual care of women with breast cancer. And it raised doubts about the treatment's cost-effectiveness, saying it was concerned the test could be performed in only one US laboratory.

Melbourne breast surgeon Dr Jane O'Brien said the MSAC was missing the point. The test was not about saving lives but about stopping the over-treatment of women with chemotherapy that made no difference, she said. The test, measuring the expression of 21 cancer-related genes, is performed on a small amount of tissue removed during a lumpectomy.

Study results show that of every 100 patients tested after being prescribed chemotherapy and hormone therapy, 65 would be switched to hormone therapy only. Of every 100 patients prescribed hormone therapy only, 15 would be switched to chemotherapy as well. Between 900 and 2000 Australians a year would benefit from funding of the test.

It would cost \$3-\$6 million per annum, but this would be offset by savings from reduced chemotherapy, making the net impact \$1.5-\$3.5 million. A spokesman for Health Minister Greg Hunt said the committee was independent and had made its decision based on expert advice.

Opposition health spokeswoman Catherine King said genomic testing for cancer was the way of the future, and governments needed to do more.

The Australian: 5 October, 2017

The Australian

By Sarah-Jane Tasker 5 October 2017

Patients Forced into Chemo: No Funds for Breast Cancer Testing

Globally recognised technology that could spare thousands of Australian breast cancer patients from unnecessary chemotherapy will remain out of reach for many after the federal government refused to fund the expensive test.

The test, which provides a prognosis for early-stage breast cancer patients on the likelihood the cancer will recur, is reimbursed in the US, Canada, Britain and throughout Europe.

Specialised Therapeutics Australia has distributed the test here since 2014 at an out-of-pocket cost to patients of \$4500, which it said was the lowest price available in the world.

More than 1000 Australian women and men diagnosed with breast cancer since 2014 have paid for the test, known as Oncotype DX.

Carlo Montagner, chief executive of Specialised Therapeutics, which applied to the government's medical services advisory committee for reimbursement of the test, said he was "dismayed and frustrated" by the latest rejection, which followed four previous failed applications.

It is believed that between 900 and 2000 Australian patients a year would benefit from the test if it was government-funded. It is estimated that funding the test would cost the government about \$3 million in the first year, rising to \$6m five years later. The test distributor said, that allowing for chemotherapy and drug cost savings, the net financial impact to the federal health budget would be between \$1.5m for the first year and \$3.5m a year at five years.

"It seems that in Australia, only the 'haves' of our society can benefit from this cutting-edge technology.

"What a pity, in this age of personalised medicine and especially at a time when the government has acknowledged a commitment to innovation," Mr Montagner said.

He said his modelling showed that more than 250 Australian women every year,

who could not afford to self-fund ODX, would endure unnecessary chemotherapy without access to the test. The genetic test identifies breast cancer patients who could safely avoid chemotherapy by analysing the activity of specific cancer genes taken from a single sample of tumour tissue.

The advisory committee said it considered the incremental benefit of the ODX breast cancer testing over optimal care remained uncertain. It also found that uncertainty regarding the cost-effectiveness of ODX remained unresolved.

Jane O'Brien, a specialist breast surgeon at St Vincent's Private Hospital Melbourne, said the decision was unjustified, given it expected ODX to be compared with "usual care".

"The purpose of the test is to identify which women may be able to avoid chemotherapy," Dr O'Brien said.

"Therefore you're not expecting it to show better survival compared to usual care.

"What you're aiming to do is to safely avoid toxic therapies in women who don't need them."

Dr O'Brien said it was clear the test could result in health savings, given the cost of ODX would be less expensive than six months of chemotherapy.

The Australian: 25 July, 2017

The Australian

By Sarah-Jane Tasker 25 July 2017

New Push for Brain Cancer Drug

Leading neurosurgeon Kate Drummond has called on the Turnbull government to break the “bureaucratic mould” and approve reimbursement of a drug that prolongs the life of Australian brain cancer patients.

The debate on access to the drug was reignited after US senator John McCain was diagnosed with an aggressive brain tumour.

Australian regulators earlier this year knocked back a request to reimburse the drug, Gliolan, which has just been approved in the US. The drug, used across Britain and Europe as standard care, “lights up” the brain tumour, which helps the surgeon to remove as much of it as possible.

More than 600 Australian patients a year could benefit from use of the drug in brain surgery but Dr Drummond, a neurosurgeon at Royal Melbourne Hospital, said because Gliolan’s definition sat between a drug and a surgical instrument it fell into a “grey area” for regulators.

“It shows that every so often something comes up that doesn’t fit the bureaucratic mould but if it’s good for patients the government should break that bureaucratic mould and get it sorted,” she said. “It is a simple thing, we know that people live longer if we remove as much of the tumour as is safely possible before a patient goes on to have radiation and chemotherapy. Anything that can help that is important.”

Dr Drummond said the price of the drug in the overall cost of a brain tumour operation was small given the greater outcome achieved. “There are several things we can do to improve a patient’s outcome but one of the things that has been proven to increase the amount of tumour that you remove is to use Gliolan,” she said.

“Some public hospitals are just wearing the cost and it is the private patients who are suffering, because if it’s not listed, most insurers won’t cover it.”

New Zealand started funding the brain tumour visualisation drug for its public hospitals from June 1 and the number of patients benefiting from the technology has already jumped. Denis Strangman, whose wife died in 2011 — 11 months after being diagnosed with a brain tumour — raised the issue of Gliolan at his recent appearance before the Senate committee into funding for cancers with low survival rates.

“I gave them verbal and written evidence on how it should be supported in Australia,” Mr Strangman, who founded the International Brain Tumour Alliance, said. He said he hoped the committee would make a recommendation, when it reported in November, to have the drug reimbursed to allow it to be more widely used in Australia to increase the quality of life of a patient and give them more time.

“The US regulator recently approved the drug and I wouldn’t mind betting that if McCain has surgery, he has surgery using that drug,” Mr Strangman said.

Southland Times: 1 June, 2017

Southland Times

By Rachel Thomas 1 June 2017

Glowing Tumours Help Patients’ Odds

It was by chance that Alice Chambers’ brain tumour was found.

The 33-year-old was loading the boot of her jeep when the window slammed down

on her head so hard “I thought someone had hit me with a baseball bat”. Days later, she noticed a broken blood vessel in her face, and decided to get it checked out, along with a small lump behind her eye.

Following a CT scan, her doctor phoned her with the message: “I’m really sorry, but they’ve found something”.

“I sort of passed the phone to my dad and slid down the wall,” she said.

Doctors had found an aggressive, malignant cancerous brain tumour known as a glioblastoma, on the right side of her head.

Two weeks ago, she became the first patient in New Zealand to be treated with a new drug that makes malignant brain tumours glow fluorescent during surgery.

The drug, Gliolan, turns tumours red while the brain mass remains blue, so the tumour can be removed down to macroscopic detail.

Before Gliolan, the average survival rate with treatment for people with standard glioblastomas was 14 months, Wellington Hospital neurosurgeon Kelvin Woon said. “I can say this in front of Alice, because I know it’s not going to be that [short] now.

“We got all of the macroscopic tumour out. And she has done very well from it.”

Previously it had been hard for neurosurgeons to distinguish between brain tissue and the edge of the tumour. Not wanting to remove brain tissue, they often ended up leaving parts of the tumour behind.

“The more tumour you remove, the better the outcome,” Woon said. “With a lower tumour burden, patients do better and live much longer, and that’s what we try to achieve.”

Chambers still needs to have chemotherapy and radiotherapy to blast any remnants of the tumour, which has turned out not to be as aggressive as first thought. The surgery has not cured her cancer, but she believes the work of Woon and Gliolan has prolonged her life.

“With the initial prognosis, the idea of never making it to 90 was the worst thing in the world.

“I was looking at my kids and knowing they’re 3 and 6 and thinking, if I’m dead in 15 months that’s 4 and 7. That’s never ever going to be old enough. You can’t leave them in the world at that age.

“I can only hope the worst is behind me, and I’ve got to look forward now and go about my life, and keep going.”

A recent Pharmac decision means Gliolan will be available to all district health boards through public funding from June 1. Woon applied to MedSafe to have it made available in 2015, and said the recent Pharmac approval was “fantastic for New Zealand”.

He estimated about 70 per cent of patients with these particular tumours would be suitable for Gliolan treatment.

Waikato Times: 1 June, 2017

Waikato Times

By Rachel Thomas 1 June 2017

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nzDoctor.co.nz: 1 May, 2017

nzDoctor.co.nz (Un-Doctored)

5 April 2017

**Breakthrough brain tumour visualisation
drug Gliolan to be listed on NZ hospital
medicines list from 1 June**

Media release from Specialised Therapeutics Group

- GLIOLAN® to be funded in all NZ District Health Board (DHB) hospitals following PHARMAC reimbursement decision
- Listing follows application by leading NZ neurosurgeon
- GLIOLAN has been shown to almost double complete resection rate and progression-free survival in brain cancer patients¹

A NOVEL drug which 'lights up' malignant brain tumours to help surgeons more thoroughly resect the cancer tissue will be widely available to New Zealand patients from 1 June, after a leading neurosurgeon applied for its reimbursement.

The drug, GLIOLAN (aminolevulinic acid HCl), assists neurosurgeons to more completely remove malignant brain tumours (gliomas) by causing them to become fluorescent during surgery.

It is expected around 100 NZ brain cancer patients a year will be operated on using this cutting-edge technology, which has been demonstrated to improve complete resection rates and almost double six-month progression free survival in patients with the most serious form of brain tumours, Glioblastoma Multiforme, or GBM¹.

It will be made available to newly diagnosed, untreated patients who are eligible for fluorescence-guided surgery.

GLIOLAN will be reimbursed subject to the following hospital restrictions:

- Patient has newly diagnosed, untreated, glioblastoma multiforme
- Treatment to be used as adjuvant to fluorescence-guided resection
- Patient's tumour is amenable to complete resection

Leading New Zealand neurosurgeon Dr Kelvin Woon made an application to PHARMAC seeking reimbursement and ensuring GLIOLAN's broad accessibility.

He has described the PHARMAC decision to list GLIOLAN on the hospital medicines list as "a big step forward".

"This is a great opportunity for NZ patients who are affected by these highly malignant tumours," he said.

“Although not curative, GLIOLAN helps us to better visualise what can be poorly-defined tumour margins, which limits our ability to resect the tumour macroscopically.

“Because we can more clearly see what is brain tissue and what is tumour, it gives us the confidence to be more aggressive and strive for maximum resection. This is important, because the evidence points to maximum (complete macroscopic) resection and increases the chances of overall survival.” ²

GLIOLAN is given to patients as a drink prior to surgery. The drug is preferentially taken up by the malignant tumour tissue.

During surgery, a neurosurgical microscope fitted with a specialised blue operating light is used, which causes cancerous tissue containing the drug to glow fluorescent pink whilst normal brain tissue appears blue. This enables neurosurgeons to better visualise these tumours and more completely remove them, whilst sparing the neighbouring healthy brain tissue.

The drug is made available in New Zealand by international biopharmaceutical company Specialised Therapeutics Ltd, an affiliate of Specialised Therapeutics Asia (ST Asia).

Chief Executive Officer Mr Carlo Montagner said several NZ hospitals had already upgraded operating theatre equipment to enable the use of GLIOLAN and neurosurgeons were preparing to use this technology as soon as the PHARMAC approval and listing takes effect.

“We are delighted to be able to provide another tool for NZ neurosurgeons to use in complex brain tumour cases,” he said.

“In this region and around the world, these patients have a very poor prognosis. With current standard chemotherapy and radiation treatment, these patients have a median overall survival of 12, maybe 15 months.³ GLIOLAN has been shown to help GBM patients survive longer without tumour progression compared to standard surgical procedures. Any drug or technology that enables patients additional time with their families is extremely valuable.”

International studies have shown that the use of GLIOLAN during brain tumour surgery has nearly doubled the rate of achieving a complete resection of the main

tumour bulk, which in turn has resulted in a doubling of the number of patients without progression of their brain cancer six months after surgery.¹

The pivotal Phase III study published in The Lancet Oncology Medical Journal reported complete resection of malignant brain tumour tissue in 65% of patients receiving GLIOLAN compared to 36% of patients in the study's control arm (difference between groups 29% [95% CI 17-40], $p < 0.0001$). Six-month progression-free survival was achieved in 41% of patients receiving GLIOLAN compared to 21% of patients who were operated on without the use of the drug (difference between groups 20% [95% CI 9.1-30.7], $p = 0.0003$)¹.

GLIOLAN was first approved in Europe in 2007 and is marketed by medac GmbH in Europe, Africa, South America and Asia (excepting Japan and Korea). Around 500 Australian patients have been operated on using GLIOLAN since 2012.

GLIOLAN will be available to purchase from May 12 from ST's New Zealand distributor, Healthcare Logistics (HCL).

About GLIOLAN[®]

The active substance in GLIOLAN, aminolevulinic acid (ALA), is a photoreceptive compound which is absorbed by cells in the body, where it is converted by enzymes into fluorescent chemicals, particularly protoporphyrin IX (PPIX). Since glioma cells take up more of the active substance and convert it more rapidly into PPIX, higher levels of PPIX accumulate in the cancer cells than in normal tissue. When illuminated under blue light of a specific wavelength, the PPIX in the tumour glows an intense red, while the normal brain tissue appears blue. This enables the surgeon to see the tumour more clearly during brain surgery and to remove it more accurately, sparing healthy brain tissue.

Like all medications GLIOLAN may cause side effects. GLIOLAN should not be used in patients with hypersensitivity to ALA or porphyrins, or in cases of acute or chronic porphyria, or in pregnancy. Cardiac disorders, gastrointestinal disorders and skin and subcutaneous disorders are all reported as being uncommon.

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About the Specialised Therapeutics Group

The Specialised Therapeutics group of companies collaborates with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life changing healthcare solutions to patients affected by a range of diseases in Australia, New Zealand and throughout South East Asia. ST is committed to making new and novel therapies available to patients around the world, with a broad therapeutic portfolio spanning oncology, hematology, urology and ophthalmology. Additional information can be found at www.STAbiopharma.com

For all inquiries, please phone Specialised Therapeutics Asia Communications Manager Emma Power on +61 149 149 525

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Pharma Dispatch: 5 April, 2017

Pharma Dispatch

5 April 2017

Specialised Therapeutics Relaunches Product for Cancer Patients

Independent pharmaceutical company Specialised Therapeutics Asia has relaunched a product used to relieve the pain of oral mucositis, a condition that can affect cancer patients undergoing chemotherapy and/or radiotherapy.

CEO Carlo Montagner said GELCLAIR was a welcome inclusion to the company's expanding oncology and supportive care portfolio.

"This product has been available in Australia before, but has been in hiatus since 2015," he said.

"We know there is continued demand for this important supportive care product and we are delighted to make GELCLAIR available once more to patients suffering from oral mucositis in Australia."

GELCLAIR is a bio-adherent oral gel that works by creating a protective film in the mouth, said the company, adding it provides relief for the painful mouth ulcers that characterise the condition, as well as improving a patient's ability to eat, drink, swallow and speak.

ST Asia will market and distribute the product under license from partner, Helsinn Healthcare SA, Switzerland. Internationally regarded oral mucositis expert Professor Dorothy Keefe said the condition could be extremely debilitating, even leading to malnutrition in some cases, with 20-40 per cent of patients receiving conventional chemotherapy affected, as well as up to 100 per cent of patients receiving radiation therapy for head and neck cancer.

"Pain in your mouth, or ulceration in your mouth, makes it hard to eat and to swallow," said Professor Keefe.

“Both of these factors have an impact on quality of life and people can lose 5-10% of their body weight if they are badly affected. GELCLAIR provides a protective barrier that reduces the pain experienced by patients, which is an important part of oral mucositis management.”

Australian journalist and broadcaster Julie McCrossin suffered the debilitating effects of oral mucositis while undergoing treatment for oropharyngeal cancer. She described the damage inside her mouth as “catastrophic”. “I would highly recommend GELCLAIR as a soothing, nurturing mouth treatment that helped me both physically and psychologically in my recovery, when I was suffering the pain and discomfort of treatment for throat cancer,” she said.

“With GELCLAIR, I actually felt it was helping me to start the road to recovery because I felt better. When you are going through weeks and weeks of trauma to your soft tissue, that is worth a million bucks.”

Herald Sun: 2 February, 2017

HERALD SUN (MELBOURNE)

By Carlo Montagner 10 February 2017

When Customers Come First, Not Dangling Carrots

I have just bought a red Tesla. It's a battery operated, engineering marvel that

doesn't require petrol, can be recharged via a rooftop solar panel, is sleek, modern and chivalrous to boot - with doors that open automatically on the owner's approach.

While I'm an unapologetic and long standing motor car tragic, what really clinched the deal was the way this beautiful piece of machinery was sold to me.

Tesla does have showrooms in Australia, but you can't actually buy these cars from a showroom.

When you go to a Tesla showroom, expert staff - obvious car enthusiasts like me - demonstrate and provide all manner of information about these cutting edge vehicles.

Our "sales" conversation was educational, informative and involved a pleasant exchange of information that ultimately, led to me purchasing a Tesla product online. At the showroom, I felt no sales pressure but was provided with enough information to make my own decision.

By being informed and well-educated by the representative, in a 'non-salesy', low pressure environment, I was free to consider the actual merits of the Tesla without the distraction of the typical car sales process. I knew the various Tesla representatives I had spoken to in the showroom were not receiving sales commissions, so the information provided was passionately, factually and legitimately delivered.

I tell this story because, as the CEO of Australia's largest independent pharmaceutical company, I have made the decision that from February 1, 2017 our in field company representatives who call on current and potential prescribers of our therapies will no longer be incentivised by the volume of prescriptions written in their territories.

Instead, financial rewards achieved by our people will be based on other performance measures - like the extent of their product and therapeutic knowledge, their level of customer service and engagement, their commitment and dedication to ensuring the patients who would most benefit from our therapies are given the best chance of accessing them.

Why are we doing this? Because if you motivate frontline representatives with a

financial carrot, then it is commonsense that those frontline staff are going to prioritise selling products instead of focusing on the specific needs of the patients the product can treat.

Like Tesla, I want doctors to know that when our field force representatives approach them about our therapies, they can engage in a legitimate and genuine exchange of information that is educational and informative.

I want them to feel comfortable in the knowledge that our representative is not being financially rewarded for 'shifting more units'.

Conversely, I want our people to be truly engaged and to make customer and patient care paramount. I want them to engage and educate without the pressure of sealing a deal.

I want them to strive to achieve - but not sales targets. Success can be measured in other ways that are still tangible.

This approach does fly in the face of how most pharmaceutical companies in Australia and around the world typically operate.

But I am convinced this is the most transparent approach. Our customers - predominantly oncologists and haematologists - can see through a sales pitch. Most consumers can, in whichever industry you work.

This is not about taking an 'airy fairy' approach to sales. Quite the contrary. As an entrepreneur with a strong commercial bent, I care passionately about the business I founded, the pharmaceutical industry and the bottom line. Without profitability, there is no pharmaceutical industry, which is able to underpin breakthrough and life saving therapies and technologies.

I staunchly believe this approach will translate to desirable commercial outcomes, because success begins with a great product that fulfils a marketplace need.

Sales are achieved when customers are educated about a product's merits and benefits. If you have the right product, then the outcome is assured.

When there is an inherent confidence in a product, there is no need to reiterate and ram home tired sales messages.

Our products are medicines that fulfil unmet medical needs. They are not 'me-too' products, but are carefully selected for in-licensing to our regions (Australia, New Zealand and South East Asia) because they are innovative and different. Like the battery operated Tesla car, they are not mainstream, but niche-market. The right people will prescribe them if they have the right information and there is a genuine medical need in the community.

Interestingly, my sales tactic sentiments are being echoed in other industries.

In recent weeks, consumer groups have called on the banking industry to come clean on how staff bonuses really work.

These groups warned that some consumers felt bullied into buying bank products by over-zealous sales people who were chasing their own bonuses, instead of providing real, transparent and legitimate information that might actually improve a customer's financial prospects instead of their own.

The customer should always come first and in the pharmaceutical industry, I would say it is even more important.

Our customers are doctors and ultimately, the patients they care for. Their health is their most prized possession. Our sales should only be made when it's right for them, based on the best information available, imparted by an expert, educated field force.

When the basics are in place, the rest will follow.

Just ask Tesla.

Herald Sun: 5 November, 2016

HERALD SUN (MELBOURNE)

By Grant McArthur 5 November 2016

Linda Defies Odds: Brave cancer survivor is determined to live life to the full

FEW people would laugh about their superannuation running out while they still have a lot of living left to do.

But for Linda Wilson, the prospect of outliving her nest egg by defying pancreatic cancer is a dream worth celebrating.

Diagnosed with terminal cancer in early 2012, the Somers 59-year-old's prognosis was so bleak she was granted immediate access to her superannuation, though not some of the drugs hoped to prolong or improve her life.

But through surgery, two rounds of chemotherapy and finally an expensive yearlong course of new drug Abraxane, she has so far defied the disease that claims 93 per cent of its sufferers within five years.

Ms Wilson has travelled Australia to go fishing, ticked items off her bucket list and bought a new car while continuing to work as a nurse.

Now she is also hoping to fight for greater attention and research for more than 3100 Australians diagnosed with pancreatic cancer each year.

"In 2013 I was told I had approximately 6-12 months to live when I asked the question, but I didn't really like the answer," Ms Wilson said.

"I am unlucky to get pancreatic cancer, but I tell you, the last 4½ years I have never lived so much."

In 2014 Abraxane was placed on the Pharmaceutical Benefits Scheme of

pancreatic cancer as a frontline therapy, but because she had already undergone other chemotherapies the \$1300-a fortnight treatment was not subsidised for her.

Other bone marrowboosting injections were also not provided for Ms Wilson because she was deemed terminal.

Fortunately for Ms Wilson, the charitable John Logan Foundation stepped in to fund her Abraxane treatment through 2015.

As Pancreatic Cancer Awareness Month kicks off this week, Ms Wilson is also preparing for a new battle. Recent scans have revealed a 2cm mass on her pancreas indicating the cancer

has returned, and doctors at The Alfred are now trying to determine if surgery to remove the organ could be successful in getting the entire cancer, or whether further chemotherapy is the best course of action.

“That is where we are at the moment. But don’t worry, I don’t give up easily,” Ms Wilson said.