New PBS Listing for Leukaemia Drug ICLUSIG™ (ponatinib)

Singapore, September 1, 2018: A DRUG currently used to treat Chronic Myeloid Leukaemia (CML) will be available on the Pharmaceutical Benefits Scheme from today as a new treatment for another aggressive form of the disease.

The drug, ICLUSIG (ponatinib) will now be available to all Philadelphia-positive Acute Lymphoblastic Leukaemia (Ph+ ALL) patients, who are intolerant or resistant to other therapies.

Leading Australian leukaemia authority, Professor Timothy Hughes, welcomed the new listing as "a major step forward" for this group of Ph+ ALL patients.

"These patients really have no prospect of long-term survival with current therapies and this PBS listing presents a really exciting new opportunity," he said.

"While outcomes for Ph+ ALL patients have improved a lot, we still have a very high incidence of relapse and resistance to imatinib and dasatinib, which have been the tyrosine kinase inhibitors (TKIs) we have used until now. Ponatinib is a potent TKI and has broad coverage against the resistant forms of leukaemia." [1]

"Essentially, the availability of ponatinib for this group of patients really does add to our capacity to provide more people with a stable, long-term response and, in some cases, the prospect of long-term remission."

ICLUSIG is made available in Australia by independent pharmaceutical company Specialised Therapeutics Australia.

Chief Executive Officer Carlo Montagner said Ph+ ALL was a highly aggressive form of leukaemia with limited treatment options.

"Unfortunately, patients who are diagnosed continue to have a poor prognosis," he said.

"There has been an urgent need for new treatments for these patients. Despite an initial complete remission rate of up to 90% following induction chemotherapy,

most adult patients will relapse and die of ALL.[2,3,4]

“We are thrilled to be making ICLUSIG available to patients for whom other treatments have failed, and providing them with a new opportunity.”

The new PBS listing follows the recent publication of five-year data from a pivotal study of ICLUSIG, known as the PACE trial.[5]

Data from this international study demonstrated that ICLUSIG is able to achieve a long lasting and “clinically meaningful” response, irrespective of dose reductions and the presence of mutations in heavily-pre-treated CML patients.[5]

ICLUSIG was first made available in Australia in 2014 for Chronic Myeloid Leukaemia patients.

For further information, please consult the full ICLUSIG Product Information.

About Specialised Therapeutics Asia

Headquartered in Singapore, 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 remains an unmet medical need. 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 ICLUSIG™ (ponatinib)

ICLUSIG is a kinase inhibitor. Its primary target is BCR-ABL, an abnormal tyrosine kinase that is expressed in chronic myeloid leukemia (CML) and Philadelphia-chromosome positive acute lymphoblastic leukemia (Ph+ ALL). ICLUSIG was designed using ARIAD Pharmaceuticals' (now Takeda) computational and structure-based drug design platform specifically to inhibit the activity of BCR-ABL. ICLUSIG targets not only native BCR-ABL but also its isoforms that carry mutations that confer resistance to treatment, including the T315I mutation, which has been associated with resistance to other approved TKIs.

About CML, ALL and the Philadelphia Chromosome

Leukemia is a blood cancer that forms in a person's bone marrow. Chronic Myeloid Leukemia (CML) is one of four main types of leukemia; it is a result of a genetic mutation that takes place in early, immature versions of myeloid cells, which form red blood cells, platelets and most types of white blood cells. Subsequently, an abnormal gene called BCR-ABL1 forms, turning the damaged cell into a CML cell. CML typically progresses slowly, but it can also change into a fast-growing acute leukemia that is hard to treat. Chronic phase (CP) is the earliest phase of CML. Patients in CP have unusually high levels of white blood cells. Symptoms are generally mild and may include fatigue, weakness, shortness of breath, fullness or early satiety and weight loss.

Acute Lymphoblastic Leukemia (ALL) starts from the early version of white blood cells, called lymphocytes, in the bone marrow (the soft inner part of the bones, where new blood cells are made). The term "acute" means that the leukemia can

progress quickly, and if not treated, would probably be fatal within a few months.

The Philadelphia chromosome is an abnormal chromosome formed when pieces of chromosomes 9 and 22 switch with each other. This forms a longer chromosome 9 and a shorter chromosome 22, which leads to the development of BCR-ABL1 and is associated with CML and Ph+ ALL.

PBS Information. Authority Required. Refer to PBS schedule for full information.

Minimum Product Information ICLUSIG™ (ponatinib HCl)

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

Indications: Adult patients with: **CML** Chronic phase, accelerated phase, or blast phase chronic myeloid Ieukaemia (CML) whose disease is resistant to, or who are intolerant of at least two prior tyrosine kinase inhibitors; or where there is a T315I mutation. **Ph+ ALL** Philadelphia chromosome positive acute lymphoblastic Ieukaemia (Ph+ ALL) whose disease is resistant to, or who are intolerant of dasatinib and for whom subsequent treatment with imatinib is not clinically appropriate; or where there is a T315I mutation. Therapy should be initiated and monitored by a haematologist with expertise in managing adult leukaemias. **Contraindications:** Hypersensitivity to ponatinib or excipients.

WARNING: VASCULAR OCCLUSION, HEART FAILURE AND HYPERTENSION

Vascular Occlusion:

Arterial and venous thrombosis and occlusions have occurred in at least 23% of ICLUSIG-treated patients, resulting in fatal myocardial infarction, stroke, stenosis of large arterial vessels of the brain, severe peripheral vascular disease (sometimes resulting in amputation), vision loss and the need for urgent revascularisation procedures. Patients with and without cardiovascular risk factors, including patients less than 50 years old, experienced these events. Monitor for evidence of thromboembolism and vascular occlusion. Interrupt or stop ICLUSIG immediately for vascular occlusion (see Precautions, Vascular Occlusion).

Heart Failure:

Heart Failure, including fatalities, occurred in 8% of ICLUSIG-treated patients. Monitor cardiac function. Interrupt or stop ICLUSIG for new or worsening heart failure (see Precautions, Heart Failure).

Hypertension:

Hypertension, including hypertensive crisis, has been observed in ICLUSIG-treated patients (26% overall, 2% serious) (see Precautions, Hypertension).

Precautions: Actively monitor and manage patients for vascular occlusions, cardiac failure, hypertension, haemorrhage, myelosuppression, hepatotoxicity, pancreatitis, QT prolongation, reversible posterior leukoencephalopathy and hepatitis B reactivation before and during treatment. Interrupt, reduce or discontinue ICLUSIG as clinically indicated (see full PI). ***Vascular occlusion:*** Do not use if history of myocardial infarction, prior revascularisation or stroke, unless the benefit outweighs the risk. Monitor cardiovascular status and optimise therapy throughout. Monitor patient for decreased or blurred vision. ***Cardiac failure:*** Monitor for heart failure and treat as clinically indicated. ***Hypertension:*** Hypertension may contribute to risk of arterial thrombotic and occlusive events including renal artery stenosis. Monitor at each clinic visit and treat hypertension to normalise blood pressure. Interrupt

treatment if hypertension is not medically controlled and consider evaluating for renal artery stenosis. ***Haemorrhage***, including fatalities occurred, mostly in patients with grade 4 thrombocytopaenia. Use anti-coagulants and/or anti-platelet agents with caution in patients at risk of bleeding. ***Myelosuppression:*** Severe thrombocytopenia, neutropenia or anaemia. Perform complete blood counts every 2 weeks initially. ***Hepatotoxicity:*** Including severe drug induced liver injury and fatal hepatic failure. Monitor Liver Function Tests (LFT's) at baseline and at least monthly. ***Pancreatitis and serum lipase:*** Monitor serum lipase every 2 weeks initially. ***QT prolongation:*** QT prolongation seen with other BCR-ABL inhibitors. ***Reversible posterior leukoencephalopathy syndrome (RPLS):*** Post-marketing cases of RPLS have been reported in ICLUSIG treated patients. If diagnosed interrupt treatment until event is resolved and benefit of treatment outweighs risk. ***Hepatitis B reactivation*** in patients who are chronic carriers has been observed when treated with BCR-ABL TKIs. Test patients for HBV infection prior to therapy start and consult with liver disease experts if positive. Closely monitor carriers throughout therapy. ***Lactose:*** contains lactose. ***Special populations:*** Recommended starting dose of 30 mg for patients with hepatic impairment (Child-Pugh Classes A,B & C). Caution or avoid in patients with moderate to severe or end stage renal disease, pregnancy (category D), breastfeeding, the elderly, paediatric patients, or when driving or operating machinery (see full PI). ***Interactions with Other Medicines:*** Caution with concurrent strong CYP3A inhibitors and consider a starting dose of 30 mg. Caution with CYP3A inducers, P-glycoprotein (P-gp) substrates and breast cancer resistance protein (BCRP) (see full PI). ***Adverse Effects:*** Most common (≥ 20%) adverse drug reactions (ADRs): Platelet count decreased, rash, dry skin, and abdominal pain. Most common (> 1%) serious ADRs: Pneumonia (6.5%), pancreatitis (5.6%), pyrexia (4.2%), abdominal pain (4.0%), myocardial infarction (3.6%), anaemia (3.3%), atrial fibrillation (3.3%), platelet count decreased (3.1%), febrile neutropenia (2.9%), cardiac failure (1.8%), lipase increased (1.8%), dyspnoea (1.6%), diarrhoea (1.6%), neutrophil count decreased (1.3%), pancytopenia (1.3%), pericardial effusion (1.3%). Other very common (> 10%) ADRs: Upper respiratory tract infection, anaemia, neutrophil count decreased, decreased appetite, insomnia, headache, dizziness, hypertension, dyspnoea, cough, diarrhoea, vomiting, constipation, nausea, lipase increased, ALA increased, AST increased, bone pain, arthralgia, myalgia, pain in extremity, back pain, muscle spasms, fatigue, asthenia, oedema peripheral, pyrexia, pain. This is not a full list of adverse effects – refer to full PI for more information on common

(>1%) and uncommon (>0.1%) ADRs. Dosage and administration: Monitor and manage cardiovascular risk factors before and throughout treatment. Starting Dose: 45 mg once daily, with or without food; 30 mg for patients with hepatic impairment; 30 mg with concurrent strong CYP3A inhibitors. Dose adjustments based on disease response: Consider reducing the dose of ICLUSIG to 30 mg or 15 mg for chronic phase (CP) CML patients who have achieved a major cytogenetic response, especially in subjects at risk of vascular adverse events. Consider discontinuing ponatinib if a haematologic response has not occurred by 3 months (90 days) especially in subjects at risk of vascular adverse event. Dose adjustments for toxicity: Consider dose modification or treatment cessation to manage myelosuppression, vascular occlusion, uncontrolled hypertension, pancreatitis or elevated serum lipase, and other severe adverse reactions. Provide haematologic support (platelet transfusion or haematopoietic growth factors) if clinically indicated.

- ICLUSIG to be made available to all refractory/relapsed Ph+ ALL patients from September 1, 2018
- Leukaemia expert: “Ponatinib will provide more people with a stable, long-term response…”

Reference:

1. Cortes JE et al. NEJM 2013; 369: 178321796.
2. Litzow MR. Haematology Am Soc Haematol Educ Program 2009: 362 – 70
3. Fielding AK et al. BLOOD 2007; 109 (3): 944 – 50
4. Kako S et al. Br J Haematol 2013; 161 (1): 95 – 103
5. Cortes JE et.al. Blood 2018; 132(4) 393-404I

Our CEO Discusses the Last Decade and Reveals Future Plans

Watch Video

Paul Cross is a former Federal Government ministerial advisor and senior pharma executive. Since 2012, he has been the publisher and editor-in-chief of three daily digital news mastheads covering policy, funding and politics in the Australian life-sciences sector, PharmaDispatch, BiotechDispatch and HealthDispatch. His independent news services have around 12,000 subscribers. He sat down with Carlo Montagner in August 2018 to hear how STA evolved and what its plans are for the next decade.

Paul Cross comment:

“What is unique about STA is its genesis. I can’t think of any other example of where an Australian pharma company has been privately established and then gone on to successfully commercialise products.

“Of course, you have got Australian companies like CSL. But remember, CSL began as a Government-funded entity that was privatised and then grew a global presence. Has any other company begun with only the backing of a private individual and gone on to do what STA has done?

“From a publishing perspective, what I like about Carlo is that because it is his company, he speaks with great clarity about issues relating to the pharma industry.

“He knows what he wants, when he wants it and how and why the system would benefit. STA is not a listed entity and he’s got all this skin in the game. It makes

him a great advocate for the sector.

STA holds its own among the multi-national pharma companies in Australia because it has a clear voice that comes direct from the CEO. Being independent, Carlo is not beholden to the policy directions from any global head office in New York, or London, or Paris.

“I can remember when ABRAXANE was going through the PBS process. Carlo took a really assertive view. He said, ‘This is what we are going to do, this is why it has to happen’. And it happened. That is what comes from having skin in the game.

“STA is different from the rest. This company is a great example of making things happen.”

August 2018.

Living with Multiple Myeloma: A Patient’s Story

Dot and Terry Arnold were teenage sweethearts who drifted apart but found themselves happily reunited in later life. Both had been married, but Terry was divorced and Dot had been widowed. On Terry’s retirement, they dreamed of travelling Australia in their “old caravan with new curtains”, even managing a few short trips to South Australia, New South Wales and Queensland.

Their contented new life however, was marred when doctors finally discovered why Terry was lethargic and breaking bones so easily – even by just getting out of bed. Terry became one of the estimated 1800 Australians diagnosed every year with the blood cancer, multiple myeloma1. After a stem cell transplant,

chemotherapy and a clinical trial, Terry is doing well. He knows he won't be cured "but I am hoping to keep this disease asleep and get another five or ten years."

Terry's Story

I worked in the plastics industry for 25 years and I was enjoying retirement. Dot and I did a few trips in our van but then I went to see a local doctor because I had a really sore back and I was starting to break ribs just getting out of bed. I had always been fairly fit, but one morning I got out of bed and my ribs started to crack.

It was so painful. So we went to the doctor and she ran all the tests.

When they told me it was myeloma I was shocked, we knew nothing about myeloma.

In my case, the body attacked the bone marrow. The myeloma could have been in my system for a long time. I might have had it 5 to 10 years. What triggered it, I don't know. It was so quick.

We were that shocked and we did have a little cry. But then we went to see the haematologist and he was very honest. He said we can't cure it, but we can put it to sleep for a while.

It certainly put a dent in my travelling plans!

They put me straight on to chemo and then prepared me for a stem cell transplant. I had the cell collection but about two weeks before it was due to happen my (paraprotein) levels were up and we had to put the transplant off. Then they asked me if I wanted to go on to a new trial, which meant another lot of chemo.

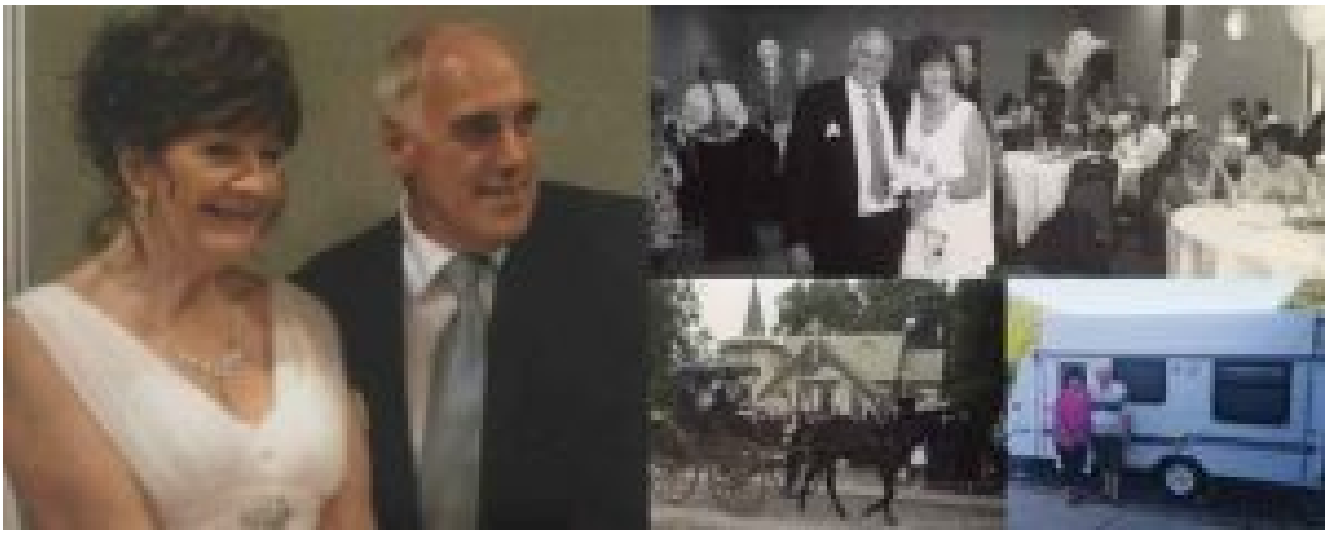
Our doctor Michael thought it was a good idea, and we trusted his leadership.

We got the levels back to where they should be and then I had the cell transplant. This was a tough time; I was in hospital for about a month.

I have been in remission for about 4 months now. It’s all going very well. I go back to the doctor at the end of every month for a blood test and you do worry about what it’s going to show up.

At the moment I am on a lot of steroid and hormone pills. Once I get off them, we want to head up north.

I don’t think I would have got through any of this without Dot. She has been marvellous. I want to keep this disease at bay and I am hoping we get another five to ten years.



Dot’s Perspective

Terry and I were childhood sweethearts. We weren’t together very long , but I dumped him. I always felt sorry about it and I always wanted to apologise, because he was really a lovely guy.

After my husband died, I asked a mutual friend how he was going. The friend put us back in touch and we caught up for dinner. I was shaking so much my cutlery was rattling.

I was worrying about how old I looked!

We got married four years ago and were looking forward to retirement.

I knew nothing about myeloma when he was diagnosed and we were shocked.

It has been tough. After the cell transplant, I did not think he would be coming out of hospital, he was so sick. Now, I just feel so relieved. He has been through a tough time and to see him suffer like this has been terrible. So, we are dusting the caravan off and I have made her some new curtains to freshen her up. We are planning on going up north.

You need to make the most of every day. None of us knows what is around the corner.

Dot and Terry would like to thank Dr Michael Lowe, Professor Andrew Spencer "and the amazing team at The Alfred for their dedication and for giving us a second chance at life".

* *Dot and Terry shared their story in February 2018.*

Specialised Therapeutics Celebrates 10 Years and Unveils Expansion Plan

Melbourne, Australia 27 August 2018: Privately-held pharmaceutical company Specialised Therapeutics Australia will today mark its 10th anniversary, unveiling new Australian headquarters and a business plan to drive healthcare innovation over the next decade.

The company, which was founded ten years ago by pharmaceutical expats Carlo Montagner and Bozena Zembrzuski with a single chemotherapy product, has emerged as the largest privately-owned Australian specialty pharma company in the region, employing close to 50 employees, generating revenues of ~$30 million and with an expansive specialty drug portfolio spanning oncology, haematology, ophthalmology, supportive care and neurology.

Officially opening new Australian headquarters in Melbourne today, Chief

Executive Officer Carlo Montagner attributed the company's success to a strategy of in-licensing mid-to late stage products for full commercialisation, but said the next 10-year plan included in-licensing earlier-stage drugs, steering them through full clinical development and globally commercialising these products. "This may require us to list a subsidiary company either on the ASX or on Singapore's SGX to co-fund compound development," he said.

"Our vision for the first 10 years was to build a profitable pharmaceutical company partnering with leading global biotech and pharmaceutical companies. While we continue to invest aggressively to further expand our global partnerships and product pipeline into new therapeutic areas, it is now time to build on these solid foundations and execute the next stage of our company's development."

Federal Treasurer, Deputy Liberal Party leader and Member for Kooyong Josh Frydenberg MP will officially unveil the company's new headquarters, noting STA's role in cementing Victoria as a major pharmaceutical and biotech hub.

"This company is an Australian start-up success story," he said. "We know that as many as 90 per cent of start-ups fail to flourish after five years. STA is a stand-out in the pharmaceutical sector and continues to grow, providing employment and generating strong revenues."

Member for Kew and Shadow Education Minister Tim Smith MP commented:

"I am delighted that Specialised Therapeutics has chosen to set up their new headquarters in the eastern suburbs of Melbourne, specifically in my electorate of Kew. Small to medium enterprises are vitally important for our local economy and community.""

Mr Montagner said: "Bozena and I are extremely proud of what we have achieved in the past decade, which has laid the foundations for our ultimate vision: to build a global pharmaceutical company delivering specialist medicines to patients where there is an unmet clinical need."

Ends.

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About Specialised Therapeutics Australia

Specialised Therapeutics Australia is an independent, international pharmaceutical company providing new specialist medicines to patients in Australia, New Zealand and across South-East Asia. Dually headquartered in Melbourne, Australia and Singapore, STA and its affiliate company Specialised Therapeutics Asia Pte Ltd collaborates with leading global pharmaceutical, biotech and diagnostic companies to bring innovative specialist therapies and technologies to patients in its key regions.It’s current portfolio includes products in oncology, haematology, supportive care, neurology and ophthalmology, but it is not confined to these therapeutic areas.

Federal Treasurer Josh Frydenberg Opens New ST Headquarters

August 2018: Australia's new Federal Treasurer Josh Frydenberg officially unveiled ST's new Melbourne headquarters, an event coinciding with the company's 10 year anniversary.

The deputy Liberal Party leader joined staff and other local dignitaries at the celebration, praising ST's commitment to innovation and recognising it's contribution to Australian healthcare.

CEO Carlo Montagner Discusses Recent Partnership Deal

This article appeared on page 36 in Pharma Asset Insights (a Scrip industry publication). Click on the Fullscreen button in the middle of the magazine below to read it or scroll down to read the article within this webpage.

"Our most recent partnership deal was with US-based Puma Biotechnology (NASDAQ: PBYI).

This novel early breast cancer drug first came to our attention in 2011 when Puma acquired the rights from Pfizer.

Following a successful FDA ODAC hearing in 2017, we reached out to Puma for an initial exploratory discussion on commercialising NERLYNX in our region. Less than 6 months later, we not only struck an exclusive license agreement , but we have submitted the New Drug Application dossier to the Therapeutic Goods

Administration (TGA) and have made NERLYNX available to appropriate Australian patients via a strictly-controlled patient access program using our proprietary access program platform.

We were able to move quickly because, as I am the 100% owner and CEO of the company, our internal review and approval processes are not subject to multiple internal senior management and board reviews. This means decision making and post-deal product commercialisation execution can be rapid.

If we make a commitment to filing a dossier on a particular date — subject to external influences beyond our control — we have always achieved that commitment.

We were looking for a drug that fulfilled an unmet need and provided a reasonable commercial opportunity.

NERLYNX overwhelmingly met these criteria. It is the first FDA-approved drug for extended adjuvant therapy in women with early stage HER2+ breast cancer and is clearly not a 'me-too' product.

In this case, due diligence processes were also expedited. Our team is comprised of senior pharma executives with many years of regulatory and commercialisation experience. With NERLYNX, we were able to rapidly assess the commercial opportunity as well as the likelihood of regulatory and reimbursement success.

Once due diligence was completed, negotiations commenced on the license terms.

Like all our agreements, the Puma deal was tailored to meet the needs of our partner. These arrangements need to be customised as our partners all have different requirements and operate in different jurisdictions.

Making NERLYNX available to women prior to TGA approval has required particular commercialisation skill.

In addition to the usual advisory boards and meeting with key stakeholders, ST also launches early access programs to potential prescribers.

These programs ensure our customers become familiar with the product, but more importantly, they enable appropriate access to patients in need at the earliest opportunity.

Our NERLYNX access program was launched in Australia in late March – four months post-deal.

We have developed a rigorous process for managing these access programs pre and post regulatory approval, and are currently operating several simultaneously.

With NERLYNX, we are targeting a reimbursement approval within 18 months of submitting our regulatory dossier.

Again, we have a strong track record of achieving these critical milestones and now look forward to making this important medicine available to appropriate Australian women."

TAILORx Explained

New findings from the landmark TAILORx study have revealed that the Oncotype DX Breast Cancer Assay is able to accurately identify the 70% of early breast cancer patients who can safely avoid chemotherapy, as well as the 30% of women for whom chemotherapy is optimal.

This investigation was the largest adjuvant breast cancer treatment trial ever conducted, with more than 10,000 women evaluated using the Oncotype DX breast cancer assay.

This test analyses 21 specific genes within a tumour to provide a Recurrence Score between 1 and 100.

In the TAILORx study, those with a Recurrence Score of 11-25 were randomised to either receive chemotherapy and hormonal therapy or hormone therapy alone and were followed up for more than nine years. Key findings presented today have demonstrated the predictive and prognostic ability of the technology – identifying those women who can avoid chemotherapy and for whom hormone therapy alone is appropriate, as well as those women for whom chemotherapy is optimal.

Australian oncologist Richard de Boer explains the importance of this outcome globally and for Australian women.

Watch the interview by clicking the link below.

Senate Inquiry Into Rare Cancer Survival

Senate Inquiry Into Rare Cancer Survival

June, 2017: A Senate Committee was appointed earlier this year, to examine why some cancers still have low survival rates. The Senate Select Committee into Funding for Cancers with Low Survival was established following concerns that there had been little to no improvement in the survival rates for some rarer cancers, including brain, liver, stomach and pancreatic cancers.

Brain Tumor Alliance Australia co-founder Denis

Strangman AM has appeared before the Inquiry, calling for broad availability of brain tumour visualisation technology.

In his opening address, he noted: “If this committee really wanted to make an impact on brain tumour treatments right now, I would suggest it recommend ways that surgeons can achieve greater resection of the tumour, and the most cost effective means is to use the fluorescence-guided agent, Gliolan. I never thought I would see the Kiwis ahead of Australia in the medical stakes, but they have put us to shame with their approval from the 1st of June with the subsidisation of Gliolan for glioblastoma patients. And, an American drugs advisory committee also recommended its reimbursement for glioblastoma less than a month ago, with a unanimous vote of 11-0. It (Gliolan) has been used in Europe for many years. Australian adult glioblastoma patients are being left behind in the possible extension of their survival. But Gliolan would be a cost-effective opportunity to redress the balance. Thank you Chair and Senators.”

To view part of Mr Strangman’s opening address, please click on the following video link.

Channel 9: 4 June, 2018

Channel 9

4 June 2018

Interview with Dr Penny Adams, Medical Expert

Interview with Dr Penny Adams, Medical Expert. There is a medical breakthrough for women with the most common form of early-stage breast cancer, with new research revealing that genetic testing could help them skip chemotherapy without affecting their chances of beating the disease. Adams says the study in women with early breast cancer has analysed the genetics of the cancer cells in a test called an Oncotype-DX, looking at 21 genes on the cancer cells and have ranked the cells into the risk of recurrence. Adams says in the past, women who are intermediate or high had gone on to have a chemotherapy. Adams says the research on 10,000 women shows that intermediate women do not benefit from Chemotherapy. Adams says the test costs US$4,000.

Adams says alternatives to Chemotherapy for intermediate patients include the removal of lumps or radiotherapy.

The Australian: 4 June, 2018

The Australian

4 June 2018

Breast Cancer Patients Can Skip Chemo: Study

CHICAGO: About 70 per cent of women with early-stage breast cancer and an intermediate risk of cancer recurrence can safely skip chemotherapy after their tumours have been removed, US researchers say.

“This is a major finding,” said Larry Norton, a breast cancer expert at Memorial Sloan Kettering Cancer Centre in New York, who helped organise the government-funded study more than a decade ago.

“It means that maybe 100,000 women in the United States alone do not require chemotherapy,” Dr Norton said.

The research, presented at the American Society of Clinical Oncology meeting in Chicago, studied how to treat women with early-stage breast cancer that responds to hormone therapy. Women were deemed to have a medium-level risk of the cancer returning based on a 21-gene panel known as Oncotype DX from Genomic Health. The test predicts the likelihood of cancer recurrence within 10 years. Those who score low on the test — from 0 to 10 — are already told to skip chemotherapy after their tumours are removed and they receive hormone therapy. Those who score high — 26 to 100 — receive both hormone therapy and chemotherapy.

The study, published in The New England Journal of Medicine, involved more than 10,000 women with breast cancer that had not spread to nearby lymph nodes and whose tumours responded to hormone therapy and tested negative for the HER2 gene. Of those, 6711 scored in the intermediate range of 11-25, and were randomly assigned hormone therapy alone or hormone therapy plus chemotherapy. The study found that all women over 50 with this type of breast cancer could skip chemotherapy, a group that represented 85 per cent of the study’s population. In addition, women 50 and younger who scored between 0 and 15 could be spared chemotherapy and its toxic side effects.

However, chemotherapy did offer some benefit to women aged 50 and younger who had a cancer recurrence score of 16-25. Steven Shak, chief scientific officer at Genomic Health, said about four in 10 women in the US with early-stage breast cancers were not tested for recurrence risk. He expected the study's results to change that practice.

"This is going to provide the highest level of evidence now for our test being indispensable in clinical practice," Dr Shak said.