Weekend Australian: 11 May, 2019

Weekend Australian

By Sarah-Jane Tasker 11 May 2019

Speed Up Cancer Funding, ALP Told

The head of Australian drug company Specialised Therapeutics, Carlo Montagner, has warned that Bill Shorten's cancer policy will not hit its target unless he overhauls the process to reimburse lifesaving treatments and puts a time frame on listing recommended drugs.

Mr Montagner said while it was a great "catch cry" to say all cancer drugs recommended for reimbursement would be approved by a Labor government, the approval process needed reviewing because it was delaying access to much-needed treatments.

"What would be more reassuring would be if Bill Shorten gave an actual time frame and said if the Pharmaceutical Benefits Advisory Committee recommended a drug, he would list it in six months," he said.

Mr Montagner also said Labor had work to do to reassure the industry, given the last time it was in government it installed a new measure that meant any drug that cost the government $20 million or more a year had to be approved by cabinet, which he said delayed drug listings.

The Opposition Leader, in his $2.3 billion cancer care package, promised that every drug recommended by independent experts would be listed on the Pharmaceutical Benefits Scheme. That promise has also been given by the Liberal Party.

"I place little weight on either government saying that as soon as the PBAC recommends a drug we will list it," Mr Montagner said. "The complexity of the processes that are required for drug approval need to be resolved first before any government can say they will list a drug as soon as it is recommended. The

recommendation part is what is really delaying access to these new lifesaving therapies."

Mr Montagner said both major parties had underestimated the complexity of first the drug approval process and then the price negotiations that took place once a drug was approved for reimbursement.

"It is clear that the process doesn't work for complex drugs and most cancer drugs are complex," he said. "It is rare that the PBAC will approve a cancer drug the first time around."

Mr Montagner's call for an overhaul of the drug approval system comes as he waits for the PBS to green light reimbursement for a new drug for multiple myeloma, which costs about $8000 a month.

The drug, Aplidin, has been approved by the Therapeutic Goods Administration, which is a world-first approval. The approval means Australian patients are the first globally to get access to this new therapy. Specialised Therapeutics is providing Aplidin to Australian patients via an exclusive licence arrangement with Spanish company PharmaMar. While the company awaits the outcome of its submission for a PBS listing, it is making the drug available in Australia through a compassionate access program.

Aplidin — which has been developed from "sea squirts" found 120m below the ocean's surface — is a new treatment option that can prolong the life of the patient. Mr Montagner said the drug was giving some patients an extra year of life. Since February, 60 Australian patients with multiple myeloma had been given the drug via the program.

"Myeloma is an aggressive disease and needs as many therapies as possible," he said. "Because Aplidin is marine derived it has this mechanism of action that is unique to the currently available drugs for multiple myeloma."

Australian Pharmacist: 1 May, 2019

AUSTRALIAN PHARMACIST

1 May 2019

Medicines Update: Nerlynx – Puma Biotechnology

A new medicine shown to significantly reduce the risk of cancer recurrence or death in an aggressive form of breast cancer has been approved by the TGA for use in Australian patients. Nerlynx (neratinib) is an oral medication taken for 12 months by women with early stage HER2-positive (HER2+) breast cancer. It is indicated for the extended adjuvant treatment of adult patients with early-stage HER2-overexpressed/amplified breast cancer, to follow adjuvant trastuzumab based therapy.

The greatest benefit is seen in women who are hormone-receptor positive (HR+) and who initiate Nerlynx therapy within 12 months of completing trastuzumab based therapy. Their five-year risk of recurrence or death is reduced by 42% after completing 12 months of Nerlynx therapy.

Professor Arlene Chan AM, from the Breast Cancer Research Centre Western Australia, described the TGA approval of Nerlynx as ‘a huge step forward’, noting that women diagnosed with HER2+ breast cancer have a one-in-four chance of cancer recurrence even after surgery, chemotherapy and trastuzumab-based therapy.

Diarrhoea was the most common side effect of the medication, but evidence was being gathered that anti-diarrhoeal medications can substantially reduce these side effects.

A reimbursement application has been submitted to the Pharmaceutical Benefits

Advisory Committee and is currently under evaluation.

New Early Breast Cancer Drug to Reduce Risk of Recurrence or Death Approved for Australian Women

19 March 2019: A NEW drug shown to significantly reduce the risk of cancer recurrence or death in an aggressive form of breast cancer has today been approved for use in Australian patients.

The drug, NERLYNX (neratinib) is an oral medication taken for 12 months by women with early stage HER2-positive (HER2+) breast cancer. It is now TGA approved with the following indication:

"NERLYNX is indicated for the extended adjuvant treatment of adult patients with early-stage HER2-overexpressed/amplified breast cancer, to follow adjuvant trastuzumab based therapy."[2]

The greatest benefit is seen in women who are hormone-receptor positive (HR+) and who initiate NERLYNX therapy within 12 months of completing trastuzumab based therapy. Their five-year risk of recurrence or death is reduced by 42% after completing 12 months of NERLYNX therapy.[3]

Leading Australian oncologist Professor Arlene Chan AM, from the Breast Cancer Research Centre Western Australia, is an international breast cancer authority and was the global study chair of the pivotal international NERLYNX registration

trial known as ExteNET.[1]

Professor Chan described the TGA approval of NERLYNX as “a huge step forward”, noting that women diagnosed with HER2+ breast cancer have a one-in-four chance of cancer recurrence even after surgery, chemotherapy and trastuzumab-based therapy.[4]

She expects that the availability of this new therapy will provide some Australian women with an opportunity to avoid experiencing a breast cancer recurrence.

“I am absolutely delighted that NERLYNX has been approved for use in Australia,” Professor Chan said.

“This is a huge benefit for women with this disease. The ability to improve the lives and reduce the risk of relapse will be enormously appreciated by many, many people in Australia.

“I would say that any proven treatment able to reduce the risk of cancer recurring has to be a win. Those women who are spared an invasive relapse will be eternally grateful that they have received this drug.”

Professor Chan noted that diarrhoea was the commonest side effect of the medication, but a new study known as CONTROL had been initiated and was now providing evidence that anti-diarrhoeal medications can substantially reduce these side effects.[2]

“We know that with appropriate and careful management, you can reduce the severity and frequency of the diarrhoea, which primarily occurs in the first month or two. Importantly, these symptoms are completely reversible.”

NERLYNX is being made available in Australia and across South-East Asia by independent pharmaceutical company, Specialised Therapeutics Asia (STA), in partnership with the drug’s US developer, Puma Biotechnology, Inc.

STA Chief Executive Officer Carlo Montagner said NERLYNX represented a new stage of treatment for Australian women and was currently being made available in Australia at no cost via the NERLYNX access program.

Mr Montagner said a reimbursement application had been submitted to the

Pharmaceutical Benefits Advisory Committee and was currently under evaluation.

“This drug currently costs more than SGD $200,000 for a full course of treatment over 12 months in North America,” he said.

“Our company is currently making NERLYNX available to appropriate women in Australia free of charge prior to PBS approval. However, we are concerned many eligible women may not be aware of this access program and therefore may be missing out on a potentially life-saving treatment.

“Every woman who has been diagnosed with HER2+ early breast cancer and is either currently taking trastuzumab-based therapy or has completed a course of trastuzumab-based therapy in the past 12 months, needs to be aware of this program and discuss with their oncologist whether it is appropriate for their condition.

“With this TGA approval, this is the first time Australian women are being presented with an opportunity for *extended*-adjuvant therapy that will reduce the risk of disease recurrence in some women who would otherwise have had a relapse.

“We are pleased to be at the forefront of this new treatment paradigm and look forward to changing outcomes for these women and their families and friends.”

Puma Biotechnology’s CEO and President Alan H. Auerbach added: “Reducing the risk of disease recurrence remains a need for patients, despite advances in the treatment of early-stage HER2-positive breast cancer. We are pleased that our partner STA will be bringing this new medicine to patients throughout Australia and would like to express our appreciation to the patients, caregivers and physicians who contributed to the neratinib clinical development program and more specifically, the ExteNET trial. We are committed to continuing to expand NERLYNX accessibility to patients around the world.”

Ends.

About NERLYNX

NERLYNX (neratinib) is an irreversible tyrosine kinase inhibitor that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER[4,5,6]

NERLYNX is the first HER2-targeted medication approved by the FDA 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).[4] NERLYNX is also the first anti-HER2 treatment to be EC-approved as extended adjuvant therapy for early stage HR+ / HER2-positive breast cancer following adjuvant trastuzumab-based therapy.[5,6]

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.

Click on this link for AU Product Information:
https://www.stabiopharma.com/assets/files/d-nerlynx_pi.pdf

Click on this link for US prescribing information:
https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208051s000lbl.pdf

Click on this link for EU prescribing information:
https://www.ema.europa.eu/en/documents/product-information/nerlynx-epar-product-information_en.pdf

About HER2+ Breast Cancer

Approximately 15−20% of breast cancer tumours over-express the HER2 protein. HER2+ 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 returning after surgery, up to 25% of patients treated with trastuzumab-based adjuvant therapy experience recurrence.[4]

About the ExteNET Study[1,6]

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

The ExteNET trial randomized 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%.[7]

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-based therapy.[3]

The most common adverse reactions (≥ 5%) were diarrhoea, nausea, abdominal pain, fatigue, vomiting, rash, stomatitis, decreased appetite, muscle spasms, dyspepsia, AST or ALT increase, nail disorder, dry skin, abdominal distention, epistaxis, weight decreased and urinary tract infection.[2]

Puma is conducting a Phase II 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.[2]

About Specialised Therapeutics Asia

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

Further Inquiries

Emma Power, Corporate Affairs and Communications Manager, Specialised Therapeutics Asia +65 3158 9940 or +61 419 149 525 or epower@stbiopharma.com

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3AW: 19 March, 2019

3AW

19 March 2019

Interview with Dr Richard de Boer, Oncologist, Peter MacCallum Cancer Centre

Interview with Dr Richard de Boer, oncologist, Peter MacCallum Cancer Centre. Mitchell says it has been discovered a drug is effective in reducing the chance of relapse of breast cancer. De Boer explains this drug has been approved by the TGA now but it is not yet on the PBS. De Boer states this drug is specifically for those with HER2-positive breast cancer. De Boer states this drug reduces the chances of HER2-positive breast cancer returning by 25%. He states Specialised Therapeutics, which is bringing this drug to Australia, has opened a scheme that will see the drugs given for free to patients until the drug is listed on the PBS. Mitchell says this drug looks very promising.

Herald Sun: 19 March, 2019

HERALD SUN (MELBOURNE)

By Aleks Devic 19 March 2019

Breast cancer hope: Regulator green-lights treatment

A NEW breast cancer wonder drug has been approved for use in Australia from today.

Women diagnosed with the aggressive HER2+ breast cancer have a one in four chance of relapse, even after surgery and chemotherapy. But test data has shown the drug, Nerlynx, reduces the five-year risk of death or recurrence in women with earlystage HER2+ by 42 per cent.

The Therapeutic Goods Administration has now approved use of the drug.

Pharmaceutical company Specialised Therapeutics is lobbying the federal government to put the drug, which in North America costs $200,000 for a full 12-month course of treatment, on the Pharmaceutical Benefits Scheme. But for the moment, the drug is available free via an access program. Specialised Therapeutics and the drug's developers, Puma Biotechnology Inc., will absorb the cost.

Nationally, it is predicted that 19,371 women will be diagnosed with breast cancer this year, and it is estimated that 20 per cent of all newly diagnosed women will have HER2+ early breast cancer. Oncologist Professor Arlene Chan,

AM, from the Breast Cancer Research Centre Western Australia, said the drug would improve lives and dramatically cut relapse risks. Prof Chan, who was involved in trials of Nerlynx, said: “Those women who are spared an invasive relapse will be eternally grateful that they have received this drug.”

Breast Cancer Network Australia chief executive officer Kirsten Pilatti said the drug provided patients with additional treatment options. “What we do know is the fear of the breast cancer returning is one of (patients’) greatest fears,” Ms Pilatti said. “Any treatment option that can reduce a woman’s risk of recurrence is not just great from a cancer perspective but also from an emotional perspective,” she said. “This is a great first step.”

Women are being urged to consult their oncologist about whether the drug is a suitable treatment for them. And they are being reassured that it will not leave them out of pocket.

Kate Harper, who was diagnosed with the HER2+ breast cancer when her twin boys were aged just six, has begun treatment with Nerlynx. “I have two young children. I have got a lot to live for. I have always said I will do anything and everything I can to give myself a chance and my children a chance,” she said.

Doctors say the most common side effect of the drug is diarrhoea, which data suggests treatment can reduce.

West Australian: 19 March, 2019

The West Australian (Perth)

19 March 2019

Cancer Drug Nod

A new breast cancer wonder drug has been approved for use in Australia from today.

Women diagnosed with the aggressive HER2+ breast cancer have a one in four chance of relapse, even after surgery and chemotherapy. Nerlynx reduces the five-year risk of death or recurrence in women with early-stage HER2+ by 42 per cent.

For the moment the drug is available free via an access program.

International Women's Day

March 8 is International Women's Day. Today, we recognise the clinicians, patients and our colleagues whose stories always inspire us to be better at work, and in life. We know everyone has a story. These three women have generously shared some of the diverse experiences that have shaped their lives and careers.

Kate's Story

Royal Melbourne Hospital Head of Neurosurgery Associate Professor Kate Drummond toyed with the idea of teaching and science before finding her way into medicine. Born and bred in Sydney, she credits her parents for inspiring her academic achievement, with their never-ending encouragement instilling a firm belief she could do anything. And while brain matter is interesting enough, it is the people she treats every day who matter most. In this piece, she explains her motivation and outlines her next mission to improve global health.

You were the first person in your family to attend university. What inspired this brilliant career?

I don't think it was anything other than parents who were just totally encouraging. I was the long-awaited child of adoptive parents. They had been waiting for me for a long time and my Mum and Dad poured all their love into me. I was read to, constantly encouraged and told I could do anything. It did not strike me at the time, but this sort of culture of achievement was built into me and encouraged. Of course I would go to university! My family did not have medical backgrounds themselves. My mother teaches piano and my father started out as a draftsman but then worked in building management for fire protection. There are no medical people in my family at all.

It was not right until the end of school, until a teacher said to me, 'If you study hard you might get into medicine'. I thought it sounded interesting, but I was planning on teaching or maybe science. It was not until the end of school that I even considered medicine. I estimated I would need 430 out of 500 in the HSC to get into medicine at Sydney University. I had not hit 400 in my trials, but I got 431 in the finals. It was a bit of a late decision!

How did you find it initially?

I really struggled at the beginning. We did not start out training in hospitals. The first two and a bit years were sitting in a lecture theatre, learning about comparative biology and other dry basic science topics. It was not until I started seeing patients that I thought 'okay, this is what I want to do'. I started out wanting to be an obstetrician and then I delivered a baby (which really changed my mind!). Seriously though, there are a lot of things about it that made me realise it was not going to be for me. There are a lot of moral dilemmas in obstetrics. I did quite like the gynaecological surgery in my rotation. I intended on doing general surgery, but when I was an intern I had to do a term in neurosurgery to get the general surgery rotation I wanted. The rest is history.

What is it about neurosurgery that fascinates you?

A lot of people come into neurosurgery saying, 'I am really fascinated by neuroscience and the way the brain works'. It is kind of interesting, but I am actually much more fascinated by the people I look after. These are vulnerable people and I am really fascinated by how they respond and cope and be wonderful humans even when everything is going wrong.

You have been a practising neurosurgeon sine 1997. Do any patients stand out?

There are so many. But I will never forget the young woman with brain cancer who, against all odds, felt that she had to have a child despite her limited prognosis. She wanted to leave a legacy and managed to deliver twins between radiation and chemotherapy. She started off with a low grade tumour but ended up a glioblastoma. She was only in her 30s, but fell pregnant while having treatment for cancer.

Was falling pregnant against your advice? Absolutely not. My job is to make things happen if I can. This is what she desperately wanted and she achieved her goal. She had a girl and a boy and was exhausted, but joyful.

Her twins were just over a year old when she passed away. And then there was the beautiful young couple who postponed their wedding for the brain surgery. They took the wedding photos so you could not notice that one side of his face was drooping. He went through radiation and everything else. Just as they were about to go on their honeymoon, the tumour came back. He started on chemotherapy the night before they got on the plane. They went all over Europe on chemotherapy so they could still have a honeymoon. These people are extraordinary. I am always inspired by the lives that they make with what they have got. This man lived for maybe 18 months after the wedding.

Stage 4 brain cancers are incurable. What do you hope to achieve for your patients?

I want to give them the longest good quality life that we can get. Ultimately, what we hope to achieve is some cure or longer term control. But at the moment, the

reality of the job is I help them achieve their goals as best we can. I think long-term control is within our grasp. We need to translate what we are seeing in immunotherapy to other cancers. It has been disappointing so far, but sometimes it is just one piece of knowledge that drops in, like HER2 inhibitors for breast cancer and Glivec for leukaemia, or BRAF inhibitors and immunotherapy for melanoma.

What's a day in your life like?

I generally start at 6am, so I am up at 5am. I try and get a bit of paperwork done, then hit the wards at 7 am for a ward round. My days are varied: it could be all day in clinic, all day operating, it could be meetings, it could be research. Outside work, I go to movies, I go to plays, I go to the symphony. I read books, I exercise and I hang out with my family. I mostly like superhero movies. I don't want to watch movies where people are having bad things happen to them. I work with people who have bad things happen every day. I don't need to see it to have a good cry. I want happy movies.

You are now a department head. Where to from here?

Being Head of Unit was kind of my end-game. So now, I think I would like to probably have more influence in brain-tumour research. And I have a real commitment to global health education through my role as Chair of Pangea (formerly Specialists Without Borders). Growing that part of my career portfolio is something that is a real focus at the moment as well.

Tell us about Pangea, how it works and your long-term goals for this organisation.

Pangea began 13 years ago, originally as a lecture series in Africa. Basically it involves healthcare professionals from Australia and New Zealand travelling to developing countries to impart some of our knowledge to healthcare professionals working on the ground there.

These people (in developing countries) may be very good doctors, but they are living in a place where there is not very good infrastructure. What Pangea really wants to do is through education, leave behind the expertise to change the health

system. We are leaving a sustainable legacy. The lessons we leave behind will benefit health outcomes for their communities for many years. These Australian and New Zealand health professionals pay their own way to do these trips and take annual leave to be part of it all. But it is incredibly rewarding and it is great fun.

My ambition for Pangea is that it becomes a massive organisation. I want it to be the go-to organisation for global medical education needs – providing flexible, practical, scalable, targeted health education in low-resource settings. We have now done several trips to Africa, teaching our counterparts in Malawi, Zimbabwe and Rwanda.

In 2019, we are hoping to go to Myanmar and start educating health professionals in that area to improve outcomes there. The possibilities are endless. Africa we love, but I think we need to have some programs a bit closer to home.

What would you say to a young person now contemplating a medical career?

I would say 'Become a doctor'. It gives you an unlimited range of career possibilities. You might not end up in the clinical care of patients – you could end up in research, administration or international health. It is a ticket to so many fulfilling careers, in specialty practice or general practice. You don't have to worry too much about where the end point will be, it is just a great thing to do. You will find your niche.

*November 2018.

Vanessa's Story

At STA, one of our core company values is PASSION.

Senior brand manager Vanessa Vandenberg is responsible for marketing our novel brain tumour visualisation drug GLIOLAN and our first-in-class multiple myeloma drug, APLIDIN. Here, she tells of the personal experiences that have shaped her life and why this value resonates.

"I'm a strong believer that our life-experiences prepare us for a greater plan. When we face challenges, we do not always see the bigger picture, but it always become apparent – almost like 'joining the dots'.

I was only 12 years old when my mum was diagnosed with a brain tumour. I grew up in South Africa and we had to travel about 380 kilometres to a hospital for her surgery.

Mum had her first surgery to remove the brain tumour and came out of the operation fairly well. She was only 38. Unfortunately, the tumour grew back within three months and when it did, it spread into an eloquent area of her brain and she went to hospital for further surgery.

The second surgery was almost a full day, about 19 hours. When we were allowed to see her, she could only say a few words and couldn't remember or pronounce our names.

My Mum's first language was English and ours was Afrikaans. When she started

speaking again, she could only speak English, her mother tongue. She had to undergo extensive whole brain radiation, which was still very much the treatment of choice in the early 1980's.

While she did recover, her speech was permanently affected and she couldn't express herself, especially if we made her angry.

Mum survived another eight years, then died very suddenly of a brain haemorrhage. The post-mortem showed that she had an aggressive leukaemia, which was most likely the underlying cause of her haemorrhage.

It was 12 years after Mum's death that I lost my Dad to mesothelioma, a very aggressive lung cancer.

It is ironic that my professional life in the pharmaceutical industry has led me to work with oncology and haematology products. My role now is marketing two products, (brain tumour visualisation technology) GLIOLAN and (multiple myeloma therapy) APLIDIN.

I am so passionate about this role and all my life experiences have created this passion. I have never been so passionate about products in my life. I have been privileged to sell products in the oncology/haematology space, however there is something with both APLIDIN and GLIOLAN that really resonates with me.

When I speak to a surgeon about using GLIOLAN to improve the extent of resection, I want to say, 'I know what the risks (of brain surgery) because I have experienced it first hand'.

You never forget the shock of seeing your mother unable to speak, tears running down her cheek, as she tries to communicate. But she always said she just wanted to see us grow up and would have done anything to stay with us longer, even if there were deficits.

It makes me sad to think she never saw my graduation and was not there when I got married and had my son.

When I work now, I think of the extra time new therapies can give patients, even

if it is only a small amount of time. Walking down the aisle with a child, going on a last family holiday, getting married. I am passionate about extending life.

I can tell you, those few months can mean so much. Mum was there to raise us. I would do anything to have that time again. I would have done anything to have my mother at my wedding ten years later. My experiences have created my passion to help other people and their families."

**Vanessa shared her story in December 2017.*

New Early Breast Cancer Drug to Be Made Available in Singapore via Special Access Program

Singapore, 18 February 2019: A NEW breast cancer drug shown to significantly reduce the risk of cancer recurrence is being made available to women in Singapore from **today** via a Special Access Program.

The drug, NERLYNX (neratinib) is an oral medication taken by women with HER2+ breast cancer who have completed adjuvant trastuzumab-based therapy.

NERLYNX has been shown to significantly reduce the ongoing risk of recurrence in HER2+ early breast cancer patients.[1] The greatest benefit was observed in women who were also hormone-receptor positive (HR+) and treated within 12 months following completion of trastuzumab-based adjuvant therapy. Their five-year risk of recurrence or death was reduced by 42%. In these patients, invasive disease-free survival (iDFS) was 90.8% in the patients treated with neratinib, compared with 85.7% in those receiving placebo (hazard ratio = 0.58; 95% CI:

0.41−0.82; p = 0.002).

ST Asia Chief Executive Officer Mr. Carlo Montagner said a formal registration decision was not expected by Singapore's HSA before 2020, although he noted that NERLYNX is approved by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

"Data from the pivotal clinical trial tells us that the greatest benefit is seen in women who commence therapy as soon as possible after their adjuvant trastuzumab-based treatment has been completed," he said.

"Therefore, it is critical that women in Singapore who have recently completed adjuvant trastuzumab-based therapy or are about to complete adjuvant trastuzumab-based therapy, are provided access now to NERLYNX while the registration process is underway.

International breast cancer authority Professor Arlene Chan was the lead investigator and primary author in the pivotal Phase III trial of NERLYNX, ExteNET.[2]

Professor Chan said its availability in Singapore and other regions 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."

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.[3]

NERLYNX is made available in Singapore by Specialised Therapeutics Asia, under exclusive license from Puma Biotechnology, Inc.

About NERLYNX

NERLYNX (neratinib) is an irreversible tyrosine kinase inhibitor that blocks signal transduction through the epidermal growth factor receptors, HER1, HER2 and HER4.[4,5]

NERLYNX is the first HER2-targeted medication approved by the FDA 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).[4] NERLYNX is also the first anti-HER2 treatment to be EC-approved as extended adjuvant therapy for early stage HR+ / HER2-positive breast cancer following adjuvant trastuzumab-based therapy.[5]

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

Approximately 15−20% of breast cancer tumours over-express the HER2 protein. HER2+ 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 returning after surgery, over 25% of patients treated with trastuzumab experience recurrence.[6]

About the ExteNET Study[2,7]

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

The ExteNET trial randomized 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%.[7]

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.[7]

Puma is conducting a Phase II 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 commercialise 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.

Further Inquiries

Emma Power, Corporate Affairs and Communications Manager, Specialised Therapeutics Asia +65 3158 9940 or +61 419 149 525 or epower@stbiopharma.com

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World-First Approval for Multiple Myeloma Drug Aplidin®

Singapore, 11 December 2018: Australian multiple myeloma patients will have world-first access to a new first-in-class drug developed to treat the disease, following approval by Australian regulatory authorities.

The drug, APLIDIN (plitidepsin) will be available to patients who have failed or are resistant to other therapies, after the Therapeutic Goods Administration (TGA) decision to approve APLIDIN before any other country.

Leading Australian myeloma clinicians are welcoming the decision, saying APLIDIN will provide another valuable treatment option for patients.

Alfred Hospital Head of the Malignant Haematology and Stem Cell Transplantation Service, Professor Andrew Spencer, said: "APLIDIN provides a chance for some myeloma patients to extend their lives.

"We now have another drug to offer patients who have relapsed after being treated with existing therapies.

"This is important, because once patients become resistant to standard therapies, there have been very limited treatment options."

And Peter MacCallum Cancer Centre and Royal Melbourne Hospital haematologist, Professor Jeff Szer, who was the Australian principal investigator on the pivotal APLIDIN registration study, said APLIDIN had been shown to be effective and well tolerated.

He commented: "More Australian myeloma patients were enrolled into the pivotal international trial of APLIDIN than anywhere else in the world.

"These patients in the Phase 3 study known as ADMYRE have now paved the way for others to have access to a new and novel therapy.

"This really means that some patients with advanced myeloma have the possibility of improved outcomes, when previous therapies have failed."

Specialised Therapeutics will continue providing APLIDIN to eligible Australian patients at no cost via a Compassionate Access Program, prior to national reimbursement.

Chief Executive Officer of Specialised Therapeutics Asia, Carlo Montagner, said Australian regulatory authorities should be commended for ensuring Australian myeloma patients have the first opportunity to access this cutting-edge therapy.

He commented: “It is not often that Australian patients are the first in the world to access new medicines. In this case, the TGA is at the forefront, with decision-makers recognising the great need that exists in multiple myeloma. This disease remains incurable and patients eventually run out of treatment options.

The company is pursuing opportunities to provide APLIDIN to myeloma patients across South East Asia.

Specialised Therapeutics Asia has exclusive rights to market and distribute APLIDIN in Australia, Singapore and 12 other South East Asian countries under the terms of an exclusive arrangement with European partner, PharmaMar.

APLIDIN was the first drug licensed by Specialised Therapeutics Asia for the broader SE Asian market.

PharmaMar President, José María Fernández Sousa-Faro, said: “This approval for an incurable disease, corroborates the work that the PharmaMar team has done over the years with APLIDIN®. Patients and the medical community will now have a new therapeutic alternative with a new mechanism of action, that is different from the products currently in use.”

Managing Director of PharmaMar´s Oncology Business Unit, Luis Mora, added: “The approval of Aplidin® is a very important step forward for the company. This increases PharmaMar’s presence with a second drug on the Australian market and, together with our partners, we are initiating procedures for other markets, such as South America, Mexico, Canada, Asia and Israel.”

Ends.

About APLIDIN® (plitidepsin)

Plitidepsin is an anticancer agent of marine origin, originally obtained from the ascidian *Aplidium albicans*. It specifically binds to the eEF1A2 and targets the non-canonical role of this protein, resulting in tumor cell death via apoptosis (programmed death). Plitidepsin is currently in clinical development for hematological cancers, including combination studies in relapsed or refractory multiple myeloma, and a Phase II study in relapsed or refractory angioimmunoblastic T-cell lymphoma.

About Multiple Myeloma in Australia

It is estimated that around 1800 Australians are diagnosed with MM every year and 1000 people die.[1] Fewer than 50% of patients survive five-years post diagnosis.[1]

MM accounts for between 10 and 15% of all haematological malignancies and is predominately a disease of the elderly, with median age at diagnosis 65-70 years.[2] This disease typically causes increased bone osteolysis resulting in pathological fractures, renal failure, hypercalcaemia, immune suppression, increased infection risk and bone marrow failure.[2]

Despite significant developments in frontline, maintenance and supportive therapy options, MM remains incurable, with treatment refractory relapse eventually occurring in all patients.[3]

About Specialised Therapeutics Asia

Headquartered in Singapore, Specialised Therapeutics Asia Pte Ltd (ST Asia) is an international biopharmaceutical company established to provide innovative specialist therapies and technologies to patients throughout South East Asia, as well as in Australia and New Zealand. ST Asia's existing product portfolio spans oncology, haematology, neurology, urology and ophthalmology. Additional

information can be found at www.stbiopharma.com

About PharmaMar

Headquartered in Madrid, PharmaMar is a world-leading biopharmaceutical company in the discovery and development of innovative marine-derived anticancer drugs. The company has an important pipeline of drug candidates and a robust R&D oncology program. PharmaMar develops and commercializes YONDELIS® in Europe and has three other clinical stage programs under development for several types of solid and hematological cancers PM1183, plitidepsin, and PM60184. PharmaMar is a global biopharmaceutical company with subsidiaries in Germany, Italy, France, Switzerland and the United States. PharmaMar fully owns three other companies: GENOMICA, Spain's leading molecular diagnostics company; Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAI); and two other chemical enterprises, Zelnova and Xylazel. To learn more about PharmaMar, please visit us at www.pharmamar.com.

Further Inquiries

ST Asia Senior Manager Communications/Corporate Affairs Emma Power: +65 3158 9940 or +61 419 149 525

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Specialised Therapeutics to Collaborate with Pharmacy Phusion to Improve Patient Outcomes

Singapore, 2 November 2018: Independent pharmaceutical company Specialised Therapeutics (ST) has struck a new agreement with specialty

pharmacy services group Pharmacy Phusion to assist with the distribution and patient support for a new medicine that treats HER2 overexpressing early-stage breast cancer.

Under the terms of the agreement, patients prescribed this new breast cancer treatment by medical oncologists via the Therapeutic Goods Administration (TGA) Special Access Scheme will be contacted by a specialist pharmacist weekly for the first five weeks of treatment, and then followed up monthly for the duration of therapy.

ST Chief Executive Officer Mr Carlo Montagner said this new program was testament to the company's ongoing commitment to patient care.

"This is about reassurance," he said. "We want all patients who are being administered our products to feel supported, as well as to ensure treatment is properly initiated and managed so that the best therapeutic outcomes are achieved."

"This program is for a new medicine that ST is currently making available to medical oncologists in Australia at no cost under a strictly-controlled patient access program while undergoing regulatory evaluation by the TGA.

"We know many patients live in regional and remote communities and can encounter challenges when it comes to immediate support.

To this end, we have engaged a team of experienced pharmacists who will implement regular well-being calls to help our patients during therapy and address any other queries or concerns that may arise.

"These pharmacists will consult as required with a patient's own medical oncologist. This is not about replacing the role of the doctor or other healthcare professional – it is about ensuring all patients have access to the right support exactly when they need it."

In addition to the formal calls, patients will also be able to telephone a pharmacist for advice at any time during business hours, seven days a week.

Pharmacy Phusion's Group Professional Manager Mark Silcock said the group works across a range of complex therapy areas, but all expert pharmacists engaged in customer support programs are experienced and uniquely positioned

to support patients prescribed new and often complex medicines.

“Pharma companies not only in Australia, but around the world can benefit from having an expert pharmacist team supporting their medications,” he said.

“Our specialist pharmacists have a deep understanding of the medicines they are discussing and how they might interact with other medicines.

“We find the primary role of the pharmacist in these programs is to provide support and reassurance, which ultimately leads to improved adherence.

“Time and time again, that is what patients want – it’s not just about the medicine, but about dosage and side effects.

“Our pharmacists take the time with each individual patient to help them understand what to expect and if they do experience any side effects, to manage them appropriately and efficiently.”
The Pharmacy Phusion customer support program takes effect from today.

Ends.

Media Inquiries:
Emma Power
STA Senior Corporate Affairs and Communications Manager
Phone: +61 419 149 525

About Specialised Therapeutics Asia

Specialised Therapeutics is an international, independent pharmaceutical company established to provide pioneering healthcare to patients throughout South East Asia, as well as in Australia and New Zealand.

ST collaborates with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life changing therapies and technologies to patients affected by a range of diseases. ST remains committed to making new and novel therapies available to patients in its key regions of Australia, New Zealand and throughout South-East Asia, targeting diseases where there remains an unmet

medical 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.