ST’s Business Development Team at #BIO2018

Specialised Therapeutics delegates will attend the BIO International Convention, which returns to Boston Massachusetts this June.

Hosted by the Biotechnology Innovation Organization (BIO), the event is designed to foster global biotechnology innovation by uniting the pharma industry with biotechnology companies, academic institutions, state biotechnology centres and related organisations.

As in previous years, Specialised Therapeutics’ Business Development team will take advantage of “BIO One-on-One Partnering” networking opportunities. Our team will meet with potential new partners who have promising treatments in later stages of clinical development.

For further information about partnering with Specialised Therapeutics, please see our CEO’s latest blog or see our Partnering page.

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.

Specialised Therapeutics Asia Initiates Early Access Program for Neratinib

Singapore, 5 April 2018: Specialised Therapeutics Asia today announces the initiation of an early access program for neratinib, an extended adjuvant treatment for early-stage HER2-positive (HER2+) breast cancer.

Under this Special Access Program (SAP) select patients in Australia will be provided access to the medicine, where appropriate and when permitted by relevant regulatory authorities.

The SAP protocol allows for neratinib to be available to patients with HER2 overexpressing cancers.

In all cases, the patient must have a special clinical need that cannot be met by currently approved and available medicines.

Specialised Therapeutics' neratinib Special Access Program follows the signing of a key license agreement with Puma Biotechnology Inc. (NASDAQ:PBYI) in November 2017, providing exclusive rights to commercialise neratinib in Australia, New Zealand and in South East Asia.

Ends.

About Neratib[1]

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

Neratinib is the first HER2-targeted medication approved by the US Food and Drug Administration (FDA) as extended adjuvant treatment for early-stage HER2-

positive (HER2+) breast cancer, for patients who have previously been treated with the medicine trastuzumab following surgery (i.e., adjuvant trastuzumab-based therapy).

Extended adjuvant therapy is the next step of treatment that follows adjuvant therapy (treatment after surgery) to further reduce the risk of breast cancer returning.

Neratinib 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 Special Access Programs

Special Access Programs enable pharmaceutical companies a means of providing ethical access to off-label or unapproved medicines to assist patients where there is an unmet medical need. Enrolment in any access program is only provided following request from an appropriate medical professional. Special Access Programs are strictly overseen to ensure full compliance, and are opened when no alternative treatment options are available.

About Specialised Therapeutics Asia

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

Further enquiries: ST Asia Communications Manager Emma Power is available on +61 419 149 525.

References:

1. NERLYNX® (neratinib) US Product Information (approved) https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208051s000lbl.pdf

---

Access Program Initiated

THE AUSTRALIAN

SARAH-JANE TASKER | THE AUSTRALIAN| 5 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.

Company Update – Mar 2018

See below, ST Asia’s Company Update / Annual Report for 2017/18. To view this publication, move your mouse over the image below and click on the **Fullscreen** button in the top right corner to expand the window.

What I Have Learned Becoming a Pharma Entrepreneur

Carlo Montagner is the Chief Executive Officer and co-founder of Australia's largest independent pharmaceutical company, Specialised Therapeutics Asia. The son of working-class Italian migrants, he and his wife Bozena established the company just over 10 years ago without any institutional investment and by selling accumulated personal assets, following international careers and diverse roles inside some of the world's biggest and most successful pharmaceutical companies across Japan, Europe and in the United States. Buoyed by experience, Carlo and Bozena established Specialised Therapeutics with a single foundation product that was initially rejected, but went on to become one of the most successful chemotherapies ever commercialised in Australia. His company has since built an expansive drug portfolio, employs close to 50 staff with recently established regional headquarters in Singapore. These are his thoughts on becoming a pharmaceutical entrepreneur.

"ONE of our children aspires to eventually succeed me as the CEO of our independent pharmaceutical company. The other night she asked me, 'So Dad, what school do I need to go to and learn how I run the company?'

A straightforward question, but one that got me thinking about whether entrepreneurs really are born or made, and how you school the next generation to

innovate in pharma and to bring an entrepreneurial mindset to a high-risk, yet risk-averse environment.

Born or Made?

With the 20/20 vision afforded by hindsight, I can see that a large part of my own entrepreneurial mindset is ingrained. Yes, there have been many lessons along the way, there have been great mentors, there has been dogged determination, risk, planning, good decisions and what some may call luck or fate. There have been people and lessons along the way that helped achieve the next goal. But an inner drive to build a business and leave a legacy was part of my make-up. I doubt any of my primary school teachers would have predicted that I would one day create the largest privately owned pharmaceutical company in Australia. But I always had an inner desire to make an impact.

In my younger years, I toyed with the idea of pursuing a career in dramatic arts. However I soon realised that my acting ambition exceeded my talent. When a dramatic career appeared unlikely, I began working in a national retail chain of delicatessens to fund my university studies with the plan to become a clinical psychologist following graduation.

I quickly navigated the ranks to management and found myself at a crossroads: should I pursue retail management or stick to my psychology studies?

I loved the cut and thrust of the retail world. It allowed leadership with substantial people and fiscal responsibility, with scope to be creative and entrepreneurial. While the retail world is competitive and innovative, I decided this path long term would not provide the intellectual stimulation I enjoyed studying psychology.

It was during my post graduate studies in child psychology that I began to combine my passion for learning with my entrepreneurial vision.

I developed a plan to open a national network of specialist, education-based childcare centres. Obviously I was not the only one who saw that opportunity, but I was born into a hardworking migrant family who took on tremendous personal risk in emigrating to Australia but once established here were fiscally risk averse

to investing in anything other than bank term deposits and the family home. I had developed a similar mindset. Without the initial capital (and willingness or even basic awareness to invest in high risk capital raising activities) I could not bring these plans to fruition.
Instead with my girlfriend of the time, and now-wife Bozena Zembrzuski, we bought land (a very safe traditional investment!), before heavily researching and undertaking feasibility studies into establishing an export-centred snail farm on Melbourne's outskirts.

As a result of this research we had the confidence to invest our time and spare funds into what was, as the local newspaper reported at the time, quite a bizarre venture.

Somewhat ironically given my impending pharmaceutical career, we shelved these plans because of an extremely complicated bureaucratic landscape. There were simply too many local council and regulatory barriers in our path. While frustrated I could not build my own business at the time, I knew deep down that I wanted my own enterprise. It was about finding the right fit, at the right time.

It's a Marathon, not a Sprint

Any successful entrepreneur needs to begin with the right idea and a crystal clear vision of the targeted outcome.

To back this up, you need heavy research, sound financials and ultimately, a determination to push through inevitable barriers. When I finished my post-graduate degrees, I embarked on a role in the pharmaceutical industry, confident it would ground me in the corporate world, stretch me intellectually and meet my need to be entrepreneurial.

I set about building a solid foundation of pharmaceutical business learning. Unbeknownst to me at the time, this mission would take years. Along the way, I was offered several promotions that would improve my managerial status and salary.

I turned down several of these opportunities. Each time, despite the prospect of attractive pay increases and the recognition that comes with promotion, I knew I

had not truly achieved my current role targets.

Since my vision was to succeed across all key elements of the pharma business before I stepped into more senior roles, I decided not to move to other roles prematurely.

So, I worked with over-the-counter (OTC) products, launched a range of vitamins into supermarkets, managed mature primary care prescription products and launched several specialty hospital products. I climbed the ladder carefully, strategically and prudently. My advice to aspiring entrepreneurs? Lay the right foundation. Work internationally and gain an intimate understanding of the complex regulatory and commercial environments globally, and cross-culturally. Remember, this is a global business. It is vital pharma leaders understand all elements and intricacies of the pharma business and demonstrate tangible success in any role before taking the next step.

Manage Risk with Experience

After many years working in the pharma industry globally, one learns to cope with the many inherent risks posed developing and commercialising medicines. It is a business where more than nine out of 10 drugs typically fail to reach the market. Once in the market, medicines can still fail, due to pricing pressures or poor prescriber uptake. So we are building a business around products that have a high probability of failure, and a very small probability of meaningful success.

In my experience, it is about accepting, understanding and qualifying the risk that is evident at every stage of drug commercialisation and development.

Even if all clinical trial endpoints are met, there is no guarantee of regulatory and/or commercial success.
And when a drug is on the market – it's jumped through all appropriate regulatory hoops and been given the government tick of approval – this risk remains. A series of unexpected adverse events can quickly change how widely a product is prescribed. Many will remember what happened with Vioxx.

You have to account for factors that might be outside your control and mitigate the impact of potential market competitors.

I am emboldened by the depth and breadth of experience in this sector. If I was in the tech industry, it would be advantageous to be younger where regulatory hurdles are few and far between. But in this business, having more than 20 years' experience enables a full analysis of the potential pitfalls and factors required for commercial success.

This process ultimately enables a balanced, risk-mitigated decision. A good example of this was our decision to continue with the commercialisation of our treatment Iclusig. This highly effective therapy is prescribed for Chronic Myeloid Leukaemia and is the only treatment that works in patients with a particular genetic mutation.

Soon after launching in the US, patients reported experiencing more side effects than expected. The FDA suspended its approval and Iclusig was then (temporarily) withdrawn from the market.

There was a risk of failure if we continued with our application (for Australia). But I decided to proceed with our regulatory and reimbursement processes as I strongly believed patient benefits outweighed the risks observed in the US.

We also openly discussed with our regulators here in Australia how best we could avoid a repeat of the US experience.

Today, Iclusig has been successfully and responsibly prescribed to many patients with this disease.

Take the Leap

For many of our years working in pharma, Bozena and I often discussed how we "could do it better'. Our view was that pharma companies in general were becoming too risk averse, more bureaucratic with a greater focus on ROI rather than patient outcomes. This meant they were seeking to develop the next blockbusters and not paying enough attention to specialist medicines that fulfilled an unmet medical need in patient groups with unique but rarer diseases.

Find Great Mentors

Mentors are vital to young entrepreneurs and I have had several but two stand out.

Pascal Soriot is the global chairman and CEO of Astra Zeneca. He brought me from Australia to the US in a senior role. From him, I learnt the importance of attention to detail and being data driven. He taught me that facts and numbers reveal the 'truth' and should underpin key strategic business decisions. He also instilled a belief that gut instinct alone is not a decision making tool on which to rely.

Pascal also taught me to treat a business as if it was your own.

He taught this by example, when he critically reviewed, sometimes painfully so, all key commercial recommendations by any of his direct reports, regardless of seniority and experience, with the sole objective of ensuring it was the right decision for the organisation. He was not only a key mentor in management skill, but in demonstrating how passion drives sound business decisions.

My other stand-out mentor was US entrepreneur and philanthropist Patrick Soon-Shiong. He is a complex man who invented Abraxane, the drug that eventually became STA's foundation product. When one reads his history from working as an underpaid surgeon in apartheid South Africa, through to becoming a billionaire entrepreneur, there can only be admiration for his ability to persist through adversity against many 'naysayers'.

As a surgeon and entrepreneur, he was a risk taker who persisted when he believed that developing Abraxane would provide a solution to a problem others could not see. He did this despite seemingly more experienced or more knowledgeable people advising him that his idea would amount to nothing. Ultimately, he taught me to be persistent and not to let negative voices cloud your vision.

Stick to your Knitting

"Sticking to your knitting" is an old but valuable adage and in my mind, it is

essential to business success.

You must stick to what you know. In my case, it's pharmaceuticals. If, after all these years, I cannot successfully commercialise a drug, then there's something wrong with me!

I can also see that when entrepreneurs diversify too quickly that they start making bad decisions. Look at (Australian businessman) Alan Bond when he bought the Channel 9 media company. He was a successful entrepreneur but knew nothing about running a television network. My view is that ego probably got in the way, as did the need to expand too quickly. He ended up selling the company back to Kerry Packer for reportedly less than half the original sum. So the message here is, don't let ego take over and don't expand too quickly. Stick to what you know, continually evolve and refine your skills. Only then can you execute with confidence.

Building a Pharmaceutical Company from the Ground Up

When I started Specialised Therapeutics, I understood the principles of making a pharma drug successful, but I did not understand the 'nuts and bolts' of putting a business together.

This was an enormous challenge. When you work in big pharma, it is a well-oiled machine and the groundwork is well established. We had to live and learn. No-one is born knowing everything and there is no handbook to starting and running a pharmaceutical company, because it is such a unique business. We learned our business lessons along the way, sometimes the hard way. Even the hard lessons have enriched our experience. I am proud of what we have developed and it was what we had in mind all along: we wanted an agile commercial business with a team that was able to make decisions and bring products to market quickly. We don't have a lot of the red tape that exists in larger pharma companies. This means we can get products to market and patients quickly and as seamlessly as possible.

A CEO’s Biggest Challenge

The biggest challenge is bringing the right people into our company who are aligned not only intellectually, but culturally. As we grow, we are mindful of attracting and retaining the right people with the right qualifications, who have the same sense of urgency and ideals.

From a commercial perspective our challenge is to continue building the portfolio. This is the ‘leaky bucket syndrome’.

You can in-license a great product but as soon as a patent is granted you have a finite window to maximise the commercial opportunity. It is our endeavour to keep filling the leaky bucket to ensure the company keeps evolving and growing. This means staying one step ahead, and being aware of the wider regulatory framework nationally and internationally. You need a global perspective and an awareness of key health demographics and policies.

Look to the Future

When there are difficult times and difficult decisions, it can help to project forward. I think to myself, ‘In 1, 2, 3 years from now I will say, the outcome was well worth the adversity faced and the effort invested’.

I do not have a numbers target for what I want this company to be worth. Bozena and I do not define the success of the company by numbers alone, but rather what it achieves by contributing to society. Sure we need to be profitable, and the more profit we generate, the more we can contribute to society by making available medicines that really make a difference to people’s lives. In turn, this makes our lives more meaningful.
I had a deliberate strategy for building my career, and my goal now is to keep strategically building upon STA’s foundation, and grow organically. A strong and sound corporate ballast will underpin further success.

I have no doubt that we will be a bigger company in the next few years. But I am determined that the same core values behind our early success will shape our future.

I am driven by a need to keep improving and not accept the status quo. Good enough is never good enough.

What does Success Look Like to a Pharma CEO?

Very simply, being successful in pharma is bringing to market a drug that meets the needs of a patient.

You may have the best science in the world, you may bring products to the point of commercialisation, but if they are ultimately rejected by authorities like the Therapeutic Goods Administration and the PBS, you have nothing.

So, finally getting that medicine to the right patient at the right time so it improves real world outcomes for patients and their families, while managing to do this profitably, is the only real measure of success in this business.

Back to the Original Question – Are Entrepreneurs Born or Made?

So returning to the original question of whether entrepreneurs are born or made. My own conclusion is that fundamental entrepreneurial attributes are hard-wired.

However, these innate personal characteristics need to be nurtured by the right mentors at critical development stages in order for potential to be realised.

An entrepreneurial mindset is never a guarantee of success. But the right people and the right learnings combined with that mindset will give that entrepreneur the best chance to reach their full potential.

Carlo Montagner, February 2018

Access Programs and Why We Need to Tell Physicians About New Medicines Available to Patients

When it comes to healthcare, Australians are fortunate.

We have a world-class health care system that includes an amazing government initiated and managed scheme to ensure that new drugs – perhaps already approved internationally — can be made available in this country, with the approval and supervision of treating doctors.

This scheme is known as the Special Access Scheme (SAS) and was introduced by Australia's Therapeutics Goods Administrations (TGA) "in recognition that there are circumstances where patients need access to therapeutic goods that are not on the ARTG". (https://www.tga.gov.au/form/special-access-scheme).

The motive driving the TGA to initiate the SAS scheme is laudable. However, I continue to hear of many cases, specifically in oncology and haematology, where

physicians are completely unaware that special access programs exist.

I recently heard about a patient with a life-threatening illness who sold his home to import and fund access to a new, innovative and expensive cancer therapy that was not yet approved for use in Australia.

But unbeknownst to both the patient and his physician, there was a special access program – fully compliant with Australia's laws – that would have enabled him access to this unapproved medicine with significantly less financial sacrifice.

Further, this access program was initiated by the pharmaceutical company that developed, manufactured and ultimately imported the drug into Australia for the specific purpose of enabling Australians access to this cancer therapy prior to its regulatory approval.

And herein lies one of the great dilemmas facing pharmaceutical companies developing specialty medicines.

Under the Medicines Australia Code of Conduct, proactively communicating information to a medical professional about the availability of any unapproved drug via an access program under the auspices of the TGA SAS is forbidden, as it is seen to be advertising or promoting an unapproved specialist medicine.

This is where I say – and many of my medical oncologist and haematologist colleagues agree– that there has to be a rethink.

MA must acknowledge that there is a significant difference between advertising and informing.

At the very least, we must have absolute confidence in the decision making process our health care professionals undertake when considering prescribing an unapproved therapy.

These decisions are being made by highly educated, intelligent professionals who have dedicated their lives to medicine. These doctors are not going to provide a medicine to a patient just because they have heard about an access program. They will research information to make the right decision, for the right patient, at the right time.

Given the tremendous workloads of specialist physicians, it is unreasonable to

expect that they would be fully aware of all available access programs. And there are many, as numerous innovative therapies have emerged in recent years. My company alone has several access programs in place.

The pharmaceutical industry should be encouraged to ensure all appropriate physicians are made aware of any access programs responsibly, and without making any promotional claims about the efficacy and safety of these medicines.

This information will enable physicians and patients to make informed and timely decisions about whether they wish to access the unapproved drug.

More broadly, patient and public health lobbyists are also calling for access program information to be available via a central national database, so physicians and patients are aware which new therapies might be available, albeit with special provisions.

Such a database would ensure that the intent of the TGA's SAS is fully realised, ensuring all Australians have the opportunity to access innovative but unapproved new medicines, when deemed appropriate by their physician and when strictly supplied by legitimate medicine manufacturers and developers.

New Early-Breast Cancer Drug to be Made Available in Australia, New Zealand and South East Asia following License Deal

Singapore, 23 November 2017:

A NEW breast cancer drug shown to reduce the risk of cancer recurrence will soon be made available in Australia, New Zealand and throughout South-East Asia, following a key license deal between Specialised Therapeutics Asia (ST Asia) and US biopharmaceutical company Puma Biotechnology, Inc. (NASDAQ: PBYI).

Under the terms of the exclusive arrangement, Specialised Therapeutics will market the drug NERLYNX® (neratinib) throughout the Asia-Pacific, beginning with Australia, Singapore, Malaysia and Brunei.It will be available to women with early-stage, HER2+ breast cancer following standard of care adjuvant chemotherapy and 12 months of trastuzumab-based therapy.

Commercial terms of the agreement are not being disclosed, but Puma will receive an upfront payment as well as milestones and other payments on NERLYNX sales in all ST Asia regions.

NERLYNX is the first treatment to be FDA approved for extended adjuvant therapy in early-stage HER2+ breast cancer following adjuvant trastuzumab-based therapy.

Results from a double blind, placebo-controlled, randomised Phase 3 study showed that NERLYNX reduces the risk of invasive disease recurrence or death by 27% compared to placebo after a median follow up of 5.2 years. The 5-year invasive disease-free survival (iDFS) rate for the NERLYNX arm was 90.2% compared to 87.7% in the placebo arm (p=0.008).[1]

For the pre-defined subgroup of patients with hormone receptor positive disease, approximately 57% of the overall study population, the results of the trial demonstrated that at 5 years, treatment with neratinib resulted in a 40% reduction of risk of invasive disease recurrence or death versus placebo (hazard ratio = 0.60, p = 0.002).[3] In this sub-group, the 5-year iDFS rate for the neratinib arm was 91.2% compared to 86.8% in the placebo arm.[1]

The safety results showed the most frequently observed adverse event for the NERLYNX-treated patients was diarrhoea, with approximately 40% of the NERLYNX-treated patients experiencing grade 3 or higher diarrhoea (1 patient (<1%) had grade 4 diarrhoea). Patients who received NERLYNX in this trial did not receive any prophylaxis with anti-diarrhoeal agents.[1,2]

Principal trial investigator, Professor Arlene Chan, said the availability of NERLYNX in Australia and other regions was an important step forward in further reducing recurrence in HER2+ early breast cancer.

“This is a drug that provides a potential cure for some women who may otherwise have had a recurrence,” she said.

“Despite the clear proven benefit of standard of care chemotherapy and trastuzumab therapy, one in four women diagnosed with early-stage HER2+ breast cancer can still have a relapse within five years.

“This drug will now prevent some of those women from experiencing that recurrence.

“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.”

Specialised Therapeutics Chief Executive Officer Carlo Montagner said NERLYNX was a valuable inclusion to the company’s expanding oncology portfolio.

“We are thrilled to be able to provide this therapy to women in our regions, working in collaboration with our new international partner, Puma Biotechnology,” he said.

“We plan to expedite access to this important medicine, with a Special Access Program to open in Australia in Q1 2018. This will provide early subsidised access for appropriate patients. In tandem, we will file for TGA registration and seek regulatory approval to market in other regions, including Singapore, Brunei, Malaysia and New Zealand.”

President and CEO of Puma Biotechnology Alan H. Auerbach said this license agreement demonstrates the commitment to bringing NERLYNX to patients around the world.

“We are confident this new partnership with ST Asia will ensure all appropriate patients in the region can access this new medicine at the earliest opportunity,” he said.

NERLYNX is an oral medication taken after chemotherapy and after 12 months of treatment with a trastuzumab-based therapy, which is the global standard of care.

About NERLYNX[4]

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

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

Extended adjuvant therapy is the next step of treatment that follows adjuvant therapy (treatment after surgery) to further reduce the risk of breast cancer returning.

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

About HER2+ Breast Cancer

Approximately 20% to 25% 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 24% of patients treated with trastuzumab experience recurrence.[1]

About the ExteNET Study[1, 2]

The ExteNET trial was a double-blind, placebo-controlled, Phase III trial of neratinib versus placebo after adjuvant treatment with trastuzumab (Herceptin)

in patients with early-stage HER2-positive breast cancer.

The ExteNET trial 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 extended adjuvant treatment with either 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 in the trial.

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%.

A secondary endpoint of the trial was invasive disease free survival including ductal carcinoma in situ (iDFS-DCIS). The trial demonstrated that treatment with neratinib resulted in a 29% reduction of risk of disease recurrence including DCIS or death versus placebo (hazard ratio = 0.71, p = 0.004). The 5-year iDFS-DCIS rate for the neratinib arm was 89.7% and the 5-year iDFS-DCIS rate for the placebo arm was 86.8%.

For the pre-defined subgroup of patients with hormone receptor positive disease, approximately 57% of the overall study population, the trial demonstrated that at 5 years, treatment with neratinib resulted in a 40% reduction of risk of invasive disease recurrence or death versus placebo. In this sub-group, the 5-year iDFS rate for the neratinib arm was 91.2% compared to 86.8% in the placebo arm (hazard ratio = 0.60, p = 0.002).[3]

The safety results showed the most frequently observed adverse event for the neratinib-treated patients was diarrhoea, with approximately 40% of the neratinib-treated patients experiencing grade 3 or higher diarrhoea (1 patient (<1%) had grade 4 diarrhoea).

Puma is conducting the Phase 2 CONTROL study investigating a structured prophylactic regimen of loperamide for the first 1-2 cycles of neratinib therapy.

Emerging data suggest that loperamide prophylaxis reduces the incidence, severity and duration of neratinib-associated diarrhoea as compared with events observed in ExteNET.

About Puma Biotechnology, Inc.

Puma Biotechnology, Inc. is a biopharmaceutical company with a focus on the development and commercialisation of innovative products to enhance cancer care. The Company in-licenses the global development and commercialisation rights to three drug candidates — PB272 (neratinib (oral)), PB272 (neratinib (intravenous)) and PB357. NERLYNX is approved for commercial use by prescription in the United States as extended adjuvant therapy for early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy and is marketed as NERLYNX.

Currently, the Company is primarily focused on the commercialization of NERLYNX and the continued development of its other advanced drug candidates directed at the treatment of HER2-positive breast cancer. The Company believes that NERLYNX has clinical application in the potential treatment of several other cancers that over-express or have a mutation in HER2.

Further information about Puma Biotechnology can be found at www.pumabiotechnology.com

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

Further Enquiries:

Puma Biotechnology, Inc.	**Specialised Therapeutics Asia P/L**
Alan H. Auerbach, President and CEO Mariann Ohanesian +1 424 248 6500 info@pumabiotechnology.com ir@pumabiotechnology.com	Emma Power Communications Manager +61 419 149 525Singapore Office: +65 31589940 epower@stabiopharma.com

New Early-Breast Cancer Drug to be Made Available in Australia, New Zealand and South East Asia following License Deal

- Specialised Therapeutics Asia to make NERLYNX® (neratinib) available in Australia, New Zealand and South-East Asia for women with early-stage, HER2+ breast cancer following exclusive license agreement
- Five-year follow up data shows NERLYNX reduces risk of invasive disease recurrence by 27% in women with early-stage, HER2+ breast cancer
- Special Access Program to open in Australia Q1 2018 followed by other countries in the territory

References:

1. Martin M et. al. Lancet Oncol. 2017 Nov 13: S1470-2045 [Epub ahead of print]
2. Chan A et.al. Lancet Oncol. 2016;17(3):367-77
3. Martin M. et. Al. ESMO 2017. Oral Presentation #1490.
4. NERLYNX (neratinib) US Product Information (approved) https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208051s000lbl.pdf

Our Philanthropic Heart: A Hall without Walls

Our Philanthropic Heart: A Hall without Walls

By Carlo Montagner and Bozena Zembrzuski

It was three years ago that our family decided we wanted to give and support causes beyond our local community.

After making this decision, we were made aware of the struggles facing the people of Timor-Leste.

While this region is geographically close to Australia – it's faster to travel by plane from Darwin to Dili than it is to journey between Sydney and Melbourne – the nations are poles apart, in terms of basic services, infrastructure and health and education.

When we first travelled from the capital Dili to the township of Maliana – about a five-hour journey by road – it was glaringly obvious that this community remains

emotionally and physically scarred by the country's battle to achieve independence.

But there was still a feeling of great hope and a determination to rebuild. We could also see that with the right support, young people here could be given an opportunity to really flourish.

Maliana

Our attention was drawn to the Don Bosco Technical School, which was established in Maliana to educate both boys and girls in Years 10, 11 and 12 in electrical trades.

It is proudly run by the Salesian Christian Brothers and has been purpose-built to equip young Timorese people with vital trade skills that will benefit the country's planned gas refinery operations – seen as an integral part of the country's rebuild.

We were immediately struck by the teenagers on campus. Many of them are from very poor families and travel from many parts of Timor to board. They have overcome enormous obstacles to acquire an education and take none of it for granted. They are so obviously proud to be at school, praying daily in gratitude for the simple joy of three meals a day, companionship, and the opportunity to learn.

A ‘Hall without Walls’

What they were missing on campus was a place to congregate and shelter. While there were some very basic outdoor recreational facilities, these structures provided no protection from the searing heat and monsoonal rains.

We knew that simple, but solid buildings could make a real difference to the experience of these young people and their teachers.

So, after consulting with the school principal, Brother Marcal, a Salesian Brother, we set about facilitating a build of this “hall without walls” – a structure that would shelter the exposed basketball court and provide a natural hub for community events.

Just weeks ago, we travelled back to Maliana as a family to join the students and local community for the official opening of this building (see main photo above).

We felt so privileged to be involved, and to watch as this school creates its own history.

We were genuinely humbled by the generous hospitality provided to us by this community and consider ourselves lifelong friends.

The building looks fantastic and the project is beautifully aligned with our own philanthropic goals: it is sustainable for the long term and it has the backing of the Timorese Government.

In addition, the Salesian Brothers have a long history in Timor-Leste and have

committed to operating this school for the next fifty years.

We will continue to support this school because we believe it represents the best of what Timor-Leste's future can be.

There is so much more we can do and are planning for Timor-Leste.

We look forward to providing further updates shortly of another project in the region working with younger children.

Breast Cancer Awareness Month

Breast Cancer Awareness Month

We know that on average, 1 in 8 Australian women will develop breast cancer. To acknowledge Breast Cancer Awareness Month, we share the story of Paula Beevor, who became the ‘one’ and decided to chase her dream of a new life in Australia. This is her story.

To read full text, please click on the article below.