

# Storytelling for Business



## Wellbeing newsletter prompts “outstanding” employee response

**A strong focus on wellbeing has provided a safe space for employees to share personal stories at Specialised Therapeutics Australia (STA), which has today been named an employer of choice in the Australian Business Awards.**

STA launched a light-hearted, monthly wellbeing newsletter prior to COVID-19, but made it a weekly event during the pandemic, after human resources manager Kate De Carolis “kickstarted” the inclusion of personal stories.

“It’s been outstanding, the amount that people are willing to share in those personal stories, and I think COVID has really enabled that to happen,” she says.

“People are constantly looking for that connection.”

De Carolis says employees now feel comfortable to contribute to the newsletter with their own stories – sometimes deeply personal and vulnerable – creating a virtual support network for employees.

While the newsletter is a standout feature that De Carolis says has made a

difference during COVID-19, she notes that STA offers employees a range of benefits that boost its employer value proposition, including a full health insurance allowance for employees and their immediate family members; company days off between Christmas and New Year in addition to annual leave; birthday leave; and a new program called “WEAK” (Weekend Afternoon Kickstart), allowing employees to finish work early on one Friday each month.

“All those little things we provide... really builds up to an environment where people enjoy coming to work,” De Carolis says.

---

## STA Named Employer of Choice in 2020 ABA Business Awards



**Melbourne, Australia, 8 October 2020:** Independent pharmaceutical company Specialised Therapeutics Australia (STA) has been recognised as an Employer of Choice in The Australian Business Awards 2020.

The prestigious awards recognize organisations demonstrating business innovation, product innovation, technological achievement and employee engagement via a set of comprehensive award categories.

The Employer of Choice (EOC) accolade in particular, recognises workplaces that help employees reach their full potential, via the introduction of policies and practices encouraging recruitment, engagement and retention.

STA Chief Executive Officer and co-founder Mr Carlo Montagner said STA had a long-standing commitment to recruiting and retaining outstanding employees, and further building and maintain a company culture consistent with its core values of Passion, Integrity, Teamwork, Courage and Humanity, or 'PITCH'.

"Since Bozena and I established STA 12 years ago, we have remained determined to embed these core values into all facets of our business," Mr Montagner said.

"We are an independent, family-owned pharmaceutical company that has grown from two employees in 2008 to more than 35 currently, commercialising our portfolio of specialist medicines in Australia, Singapore, Malaysia and New Zealand.

"Our independence sets us apart, not only in terms of our family values, but in how we nurture and build our workforce. We have introduced a range of initiatives to attract and retain a top-quality team who bring extensive experience in global pharma. STA is proud to be recognised by the ABA and will continue striving to remain an Employer of Choice in the Australian pharma industry."

Some of the workplace initiatives introduced by STA to encourage recruitment, engagement and retention of high calibre employees include flexible work arrangements, additional leave, Weekend Arvo Kick Start or 'WEAKS' leave, over-and-above the legally required employer superannuation contributions, outstanding health insurance benefits and ongoing training and development.

Mr Montagner added: "Workplace flexibility has been a pillar of our business to date, and will remain so moving forward. Currently, a majority of our employees are women. While we have not hired based on gender but on capability, we understand that female employees are frequently balancing work and life requirements. We have worked hard to achieve an inclusive and accommodating environment at STA that helps all team members fulfill their obligations outside work as well as enjoy career success."

ABA Program Director Ms Tara Johnston said: "Fifty-four organisations have been selected in this year's ABA Employer of Choice Awards. These organisations have

demonstrated adaptability in the workplace by utilising flexible and new ways of working and learning.

“The landscape of the workplace environment has changed rapidly, as technology has gained momentum, coinciding with businesses navigating a broad range of interrelated issues from the impact of the current challenges facing the global economy. The ability to work from anywhere, combined with the advances in connectivity tools makes us geographically neutral.

“Leading organisations have begun to implement an entirely new working environment that break down communication barriers, positioning organisations to harness the talent within their organisation, transform the employee experience and position businesses to be more resilient.”

Entrant organisations are required to demonstrate achievements across the key areas of Organisational Culture; Leadership & Strategy; Employee Education, Training & Development; Employee Health, Safety & Satisfaction; Performance Management; Recognition & Remuneration.

Organisational participation includes private companies, public companies, multi-national subsidiaries, non-government organisations, educational institutions, government departments, government agencies, local government and statutory bodies operating in Australia.

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



# ST wins Prime Healthcare Award

We are so proud, that in an exceptional field of finalists (including some of the world's biggest pharma companies) it was our breast cancer patient support program that took out top prize. Special thanks to our program collaborators Pharmacy Phusion for their support and assistance overseeing this tremendous effort.

---

## ST named as PRIME Awards finalist

At ST, we pride ourselves on customer service. We deal with healthcare professionals every day to discuss our portfolio of specialist therapies and the patients who might benefit, and we never forget that there is a person and a family at the heart of every discussion.

---

## ST Asia Executive Appointments

**Singapore, 23 July 2020:** Independent pharmaceutical company Specialised Therapeutics Asia (ST Asia) has appointed two senior executives to its Singapore team, as it drives commercialisation of new oncology products in the region.

Dr Bhuvana Ramaswamy will commence as Senior Medical Advisor for South East Asia in October, bringing extensive oncology, scientific and pharmaceutical industry expertise to the role.

Dr Ramaswamy will be joined by new Senior Business Manager Mr Kurt Sim, who has an extensive background commercialising oncology and haematology

products throughout South East Asia, along with broad regulatory and market access expertise.

STA Chief Executive Officer Mr Carlo Montagner said these appointments would bolster the company's regional presence and were further evidence of its commitment to providing new therapies to patients throughout Australia, New Zealand and across South East Asia.

"These are complex regions with nuanced regulatory, medical and commercial requirements," Mr Montagner said.

"Our regulatory team has recently achieved several new oncology product approvals in these complex regions, including Singapore, Malaysia and Brunei, with more approvals expected in coming months.

"We are building on these tremendous efforts and ensuring we have the relevant scientific and commercial personnel, with the capability to work closely with clinicians and deliver new approved therapies and technologies to South East Asian patients as rapidly as possible. Appointing senior people with intimate knowledge of these regions is imperative to executing this plan.

"We are confident these new executive appointments will enable STA to expeditiously execute its growth strategy and ensure patients have access to new therapies and technologies at the earliest opportunity."

Originally from India, Dr Bhuvana Ramaswamy moved to Singapore 20 years ago, and has been heavily involved in a number of clinical trials at Singapore's National Cancer Centre. She has held senior medical and scientific roles in the global pharmaceutical industry, including roles at Ipsen and Bristol Myer Squibb (BMS), developing relationships with oncologists across Singapore and Malaysia.

Mr Sim has acquired valuable commercial expertise in previous roles throughout the Asia Pacific, as a Regional Business Development Manager at Ipsen and in other commercial and sales management roles at global pharmaceutical companies including Roche, Wyeth and Mundipharma.

His valuable oncology and haematology networks in Singapore, Malaysia and Brunei are supported by extensive experience preparing contract agreements, regulatory access and named patient programs in numerous countries across the

region.

Dr Ramaswamy and Mr Sim will be based at ST Asia's Singapore headquarters.

**Ends.**

## **About Specialised Therapeutics Asia**

Headquartered in Singapore, Specialised Therapeutics Asia Pte Ltd (STA) is an international biopharmaceutical company established to provide 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](http://www.stbiopharma.com)

- • Key appointments to drive commercialisation of new oncology products throughout South East Asia
- • Appointments to commence October 2020

## **Further Inquiries**

Emma Power, Corporate Affairs and Communications Manager, Specialised Therapeutics Asia +61 419 149 525 or [epower@stbiopharma.com](mailto:epower@stbiopharma.com)



---

# Sarcoma Awareness Month: A/Prof Jayesh Desai



**Australians who are diagnosed with sarcoma have around a 70% chance of complete cure if they are diagnosed early, according to one of the country's leading sarcoma experts. Associate Professor Jayesh Desai says making a correct diagnosis at early stage - before the cancer has spread to other organs - is crucial to helping patients make a complete recovery. To mark Sarcoma Awareness Month, he shares some of his insights.**

“Sarcoma represents only 1% of all cancers. Although they are rare, with many patients never having heard of them before they are suddenly given this diagnosis, expert care is well set up in Australia with specialty centres in each of the capital cities. They can strike people at any age, but if a young person is diagnosed with cancer, in a significant number of cases it will be a sarcoma.

We know sarcoma is not just one disease; there are around 100 different sub-types. Sarcomas can be found in the soft-tissues or in the bone. Some rare sarcomas have known causes, but in the vast majority of cases, the cause is unknown. About 20% of soft tissue sarcomas are called leiomyosarcomas and between 30 and 40% are liposarcomas. So, in the world that I live in, these soft-tissue sarcomas are very common. And the people diagnosed with these types of



sarcoma tend to be what I call 'young middle aged'.

What would I say to someone diagnosed today? I would say that it is critically important you get expert help early. Outcomes are so much better when patients are referred to a specialist multidisciplinary unit early.

Sometimes this is hard, because sarcoma symptoms can be vague. But generally speaking, if someone has a lump that is larger than the size of a golf ball and it is located within a muscle or deep within a system, it should be investigated immediately and considered malignant until proven otherwise. That person should be referred to a sarcoma specialist for an immediate biopsy to make sure the right treatment path is adopted for that patient.

Sarcomas do vary in how fast they grow. Some can be slow-growing and others can be very aggressive. But if a sarcoma is caught early, most patients can be cured with a combination of surgery and radiotherapy. Patients with metastatic disease are occasionally still curable, but in many cases, they are not.

One of the important things I would say to patients is to make sure you have a really high-quality multi-disciplinary care team that is working together making decisions.

Research is unbelievably important, and will lead to better treatments. I think international collaboration in this area is vital. The sarcoma population in Australia for example, may be too small to gather the relevant data if we worked in isolation. But the international sarcoma community, who we work very collaboratively with, has a much broader pool of patients and therefore the ability to conduct international randomised studies with hundreds of patients; so we can confirm whether a particular treatment is effective or not. Patients should know that taking part in clinical trials remains critical for us to make a difference, and it won't necessarily mean they won't receive the best standard of care.

Looking further ahead, I think more unique treatment approaches will come from using combining existing therapies, or even newer approaches like epigenetic therapies. This will involve us potentially being able to switch genes on or off to treat particular cancers.

I have been a practising medical oncologist for about 15 years now and I was fortunate early in my career to work alongside one of the world's global sarcoma

gurus at the Dana Farber Centre in Boston. I felt a real responsibility to bring this work back to Australia.

Many, many patients I have treated have left an impression on me. I can recall a patient a number of years ago with a very rare sarcoma subtype, with was challenging to diagnose. He was only in his early to mid-twenties. That patient went on to receive immune therapy as part of a clinical trial, based on some emerging data from colleagues overseas. He has done remarkably well. That was largely because of the effort that went into his diagnosis, and international collaboration to share learnings on promising approaches. He had an atypical soft tissue sarcoma, and his treatment was “tailored” to his individual cancer. I guess the take home message here is that putting the effort into getting the right diagnosis and tailoring therapies can make a really big difference.

One of the most difficult things about my job is that often we are seeing young people with a disease that can be very difficult to treat. There is naturally a high level of anxiety with these patients and their families, something our team is particularly focused in how we support them.

But working toward a cure for those patients who are diagnosed early is very rewarding.

What is also pleasing is that our community works together very well. Not just the medical professionals and researchers, but also patients and their families, to try and come up with better treatments. Industry also plays a part in this - pharma companies are making a difference by providing new therapies and making them accessible here in Australia for our sarcoma patients, which is particularly gratifying.

There is always more work to be done but we have come a long way.”

**\* Associate Professor Jayesh Desai is a Medical Oncologist at the Peter MacCallum Cancer Centre and is also a founding member and current board member of the Australia New Zealand Sarcoma Association (ANZSA). To learn more about sarcoma, clinical trials, or to find a sarcoma specialist, please visit [www.sarcoma.org.au](http://www.sarcoma.org.au).**

---

# New Early Breast Cancer Drug Now Approved in Malaysia

**Singapore, 17 July 2020:** A NEW breast cancer drug shown to significantly reduce the risk of cancer recurrence is now approved for use in Malaysia.

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

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

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

Nerlynx was also recently approved in Singapore by the HSA.

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

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

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

“NERLYNX is the first drug in our portfolio to be approved in these regions. We

are now rapidly progressing other portfolio products through relevant regulatory channels to enable patients across South East Asia access to therapies where there is an unmet medical need.

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

Professor Arlene Chan was the lead investigator and primary author in the pivotal Phase 3 trial of NERLYNX, ExteNET.<sup>2</sup>

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

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

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

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

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.<sup>4</sup>

## **About NERLYNX<sup>5</sup>**

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

HER4.

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

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

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

## **About HER2+ Breast Cancer**

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

## **About the ExteNET Study<sup>2,8</sup>**

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

The ExteNET trial randomised 2,840 patients in 41 countries with early-stage HER2-positive breast cancer who had undergone surgery and adjuvant treatment

with trastuzumab. After completion of adjuvant treatment with trastuzumab, patients were randomised to receive neratinib or placebo for a period of one year. Patients were then followed for recurrent disease, ductal carcinoma in situ (DCIS), or death for a period of five years after randomisation.

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

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.<sup>8</sup>

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

## About Specialised Therapeutics Asia

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

- • NERLYNX<sup>®</sup> (neratinib) approved by Malaysia's National Pharmaceutical

## Regulatory Agency

- Five-year follow up data show NERLYNX reduces risk of invasive disease recurrence by 42% in women with early-stage, HER2+/HR+ breast cancer and who commence therapy within 12 months of completing trastuzumab-based therapy <sup>1</sup>
- NERLYNX expected to be available in Malaysia later this year via STA regional partner Zeullig Pharma

Additional information can be found at [www.stbiopharma.com](http://www.stbiopharma.com)

## Further Enquiries

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

## References

1. Gnant, M et al. Presented at the 41st Annual San Antonio Breast Cancer Symposium (SABCS) Dec 4-8, 2018, San Antonio, TX.
2. Chan A et.al. Lancet Oncol. 2016;17(3):367-77
3. Malaysia National Cancer Registry Report 2012 - 2016. Available online. Last accessed July 2020.
4. Singapore Cancer Registry Interim Annual Report 2010 - 2014. Available online.
5. NERLYNX (neratinib) US Product Information [https://www.accessdata.fda.gov/drugsatfda\\_docs/lab](https://www.accessdata.fda.gov/drugsatfda_docs/lab)
6. NERLYNX (neratinib) European Summary of Product Characteristics
7. Goldhirsch A et al. Lancet.2013;382:1021-1028
8. Martin M et. Al. Lancet Oncology 2017; 1-13



---

# **Biospace: 16 July, 2020**

## **BIOSPACE**

16 July 2020

### **New Early Breast Cancer Drug Now Approved in Malaysia**

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

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

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

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

Nerlynx was also recently approved in Singapore by the HSA.

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

Biotechnology Inc.

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

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

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

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

Professor Arlene Chan was the lead investigator and primary author in the pivotal Phase 3 trial of NERLYNX, ExteNET.<sup>2</sup>

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

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

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

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

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.<sup>4</sup>

## **About NERLYNX<sup>5</sup>**

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

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

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

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

## **About HER2+ Breast Cancer**

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

# About the ExteNET Study<sup>2,8</sup>

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

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

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

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.<sup>8</sup>

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

## About Specialised Therapeutics Asia

Headquartered in Singapore, Specialised Therapeutics Asia Pte Ltd (STA) is an international biopharmaceutical company established to new therapies and technologies to patients throughout South East Asia, as well as in Australia and New Zealand. STA and its regional affiliates collaborate with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life-

changing healthcare solutions to patients affected by a range of diseases. Its mission is to provide therapies where there is an unmet need. The company's broad therapeutic portfolio currently includes novel agents in oncology, haematology, neurology, ophthalmology and supportive care.

Additional information can be found at [www.stbiopharma.com](http://www.stbiopharma.com)

## References

1. Gnant, M et al. Presented at the 41st Annual San Antonio Breast Cancer Symposium (SABCS) Dec 4-8, 2018, San Antonio, TX.
2. Chan A et.al. Lancet Oncol. 2016;17(3):367-77
3. Malaysia National Cancer Registry Report 2012 - 2016. Available online. Last accessed July 2020.
4. Singapore Cancer Registry Interim Annual Report 2010 - 2014. Available online.
5. NERLYNX (neratinib) US Product Information [https://www.accessdata.fda.gov/drugsatfda\\_docs/lab](https://www.accessdata.fda.gov/drugsatfda_docs/lab)
6. NERLYNX (neratinib) European Summary of Product Characteristics
7. Goldhirsch A et al. Lancet.2013;382:1021-1028
8. Martin M et. Al. Lancet Oncology 2017; 1-13

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

SOURCE Specialised Therapeutics Asia

---

# **RxPONDER: Medical Oncologist Dr Richard de Boer**



Medical oncologist Dr Richard de Boer discusses interim results from the Oncotype DX RxPONDER study, presented at the 2020 San Antonio Breast Cancer Symposium. Click on the video banner above to watch the video.

---

## **RxPONDER: Professor Arlene Chan**



Professor Arlene Chan discusses interim results from the Oncotype DX RxPONDER study, presented at the 2020 San Antonio Breast Cancer Symposium. Click on the video banner above to watch the video.