

New Deal: ST signs new license agreement



ST has signed a third license agreement with Spanish partner PharmaMar, providing Australian patients the opportunity to access a globally-recognised sarcoma therapy. [Click for more.](#)

Breast Cancer Awareness Month: Celebrating Kee-moh Snacks



“Sometimes life guides us to where we will be the most impactful or where we will be the most fulfilled. Sometimes, that is the same place.”

Alexandra Stewart had forged a professional career as an orthoptist and was studying forensic science at university when she was diagnosed with breast cancer - just nine weeks before her wedding. She endured a double mastectomy, surgery, chemotherapy and early menopause. The side effects of her treatment were horrendous. She clearly remembers the nausea and metallic taste in her mouth, as well as the mouth ulcers and malnutrition.

She also remembers the “jelly and custard” hospital food she was served because she could not keep anything else

down and the weight loss she suffered because she was so depleted.

It was only when her treatment was all over and she'd come out the other side of breast cancer that she found her new purpose - an online food business for cancer patients called "Kee-moh Snacks", featuring recipes she designed and trialled herself with the help of nutritionists.

This business also spawned her first book, 'Festive Fare', which is a collection of Christmas-inspired recipes tailored to people undergoing cancer treatment. Now a second publication, 'Jelly is Not Food' has just been launched.

From here, Alyx dreams of Kee-moh Snacks becoming a global enterprise, informing hospitals around the world that cancer patients need foods that are nourishing, palatable and delicious.

This is her story.

"In my early thirties, I found a tiny speck of a lump in my right breast and I mentioned it to a doctor who told me it was probably just hormonal. But 18 months later, it felt like the lump had suddenly grown exponentially overnight and it had become painful. I went to my regular GP and the rest, as they say, is history. It was such a whirlwind. The following week I was into surgery. This was exactly a week after diagnosis. I had a single mastectomy initially and then I had the other breast off a year later because there were signs of pre-cancer in my other breast. Because of my age, the surgeons said to get it done.

Chemotherapy and Other Treatment

The side-effects of chemotherapy were brutal and took an inordinate toll on my body. The biggest issue was nutrition and actually being able to get food in (and stay in). Side-effects had made it so difficult to eat that I had developed disease-related malnutrition. It's very common in the cancer world but not widely dealt with. My entire diet for months (when I could eat) consisted of lamb, garlic, the

freshest white bread with the crusts removed and strawberry jam. I was so malnourished that I lost about 10 kilograms. For the duration of chemotherapy, I was also on other hormone-suppressing medication which put me into early menopause. I had hideous hot flushes. At the peak, I was having a hot flush every minute and a half. That was the most distressing thing. I had to sleep on towels on the bed because I was soaked through.

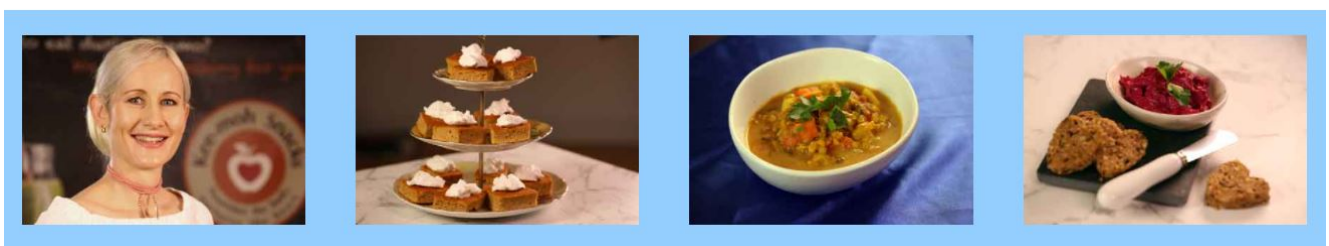
Fertility

Egg freezing was provided as an option to me early on, but we opted against it because we wanted to do everything in the shortest possible time that we could. My cancer was so hormone-positive that a pregnancy would have tipped me over the edge. I would have been putting more hormones into my body to feed that cancer.

I had not found anybody I wanted to have kids with until I met James, so it was a whole new area for me anyway. I thought he was good breeding stock! It's more these days that I think about not having children. Sometimes I wonder which one of my nieces and my nephews I will be able to rely on and if I will be lonely when I am older. I find that not having the opportunity to have children plays more on my mind now.

Work and Friends

I went back to work too soon after my chemotherapy, way too soon. It was only couple of weeks after finishing chemotherapy. It was a ridiculous move in hindsight, but I just wanted to be out of the house. Cancer can really be a lonely and isolating experience. I lost a lot of friends because I think they don't know what to say; it scares them. Nobody wants to hear the truth; they want everything to be rosy for them and for you.



Kee-moh Snacks

A few years ago, I realised I had to find my new purpose. Cancer had changed me.

I had learnt so much from my cancer experience and I realised there was something else I needed to be doing. I started listening to people with different ears. I had always enjoyed cooking, but I have found I am really good at improvising and making up recipes! I realised I wanted to give people the tools they needed to prepare nutritious and comforting food while going through cancer. That was really how Kee-moh Snacks began and the cookbooks are an extension of that.



Fear of Recurrence and the Future

It's 13 years now since my experience and I am doing well. I am fit and healthy but the fear of cancer returning is always there. I call it the 'black shadow' and it comes in waves. I don't know how I get out of it; I just need to let it run its course. I think it is becoming more prevalent now because I realise I have so much more to do. For me, it is about leaving a legacy and what if I don't get the time to do that?

If I was diagnosed with secondaries tomorrow, I think I would be in a heap. I want the time to do what I need to do.

For now, I am exactly where I am meant to be. I have never had a real feeling of purpose until now. I will never be grateful for having had cancer, but I am grateful for what it has given me."

*Alyx shared her story in August 2019.

For more on Kee-moh Snacks or to order a cookbook, please go to <https://kee-mohsnacks.com.au/>

New Drug for Diabetes-Induced Vision Loss TGA-Approved for Australian patients

Melbourne, Australia and Atlanta, Georgia, 5 August 2019: Australian patients with diabetes-induced eye disease can now access a new treatment option that provides consistent and continuous treatment with long-lasting effect.

The Therapeutic Goods Administration has now approved the drug ILUVIEN® (fluocinolone acetonide intravitreal implant), which delivers fluocinolone acetonide via a sustained release implant and provides therapeutic effect for up to 36 months.

It is available to people who have vision impairment associated with chronic diabetic macular oedema (DME), and who have been previously treated with a course of corticosteroids and who have not experienced a clinically significant rise in intra-ocular pressure (IOP).

ILUVIEN will be supplied throughout Australia by independent biopharmaceutical company Specialised Therapeutics (ST), under exclusive license from US-based Alimera Sciences, Inc (NASDAQ: ALIM).

ST Chief Executive Officer Mr Carlo Montagner said ILUVIEN was the company's first ophthalmology candidate in an expanding therapeutic portfolio.

"We are delighted to make this important new therapy available to Australian patients affected by DME, after successfully navigating what has been a complex regulatory process," he said. "Our commercial teams will now work to ensure that all appropriate patients can access this therapy at the earliest opportunity."

DME is a primary cause of vision loss associated with diabetic retinopathy. The disease affects the macula, which is the part of the retina responsible for central vision. Diabetic retinopathy causes swelling in the macula due to blood vessel

leakage, which leads to DME. Onset of the condition is painless and may go undetected until it manifests as blurred central vision, or vision loss.

Alimera President and CEO Rick Eiswirth said ILUVIEN was the only treatment providing CONTINUOUS MICRODOSING™ technology, and has demonstrated the ability to reduce oedema in the retina for up to 36 months with one intra-ocular injection, thereby enabling patients to maintain vision longer with fewer injections.

“We are thrilled that ILUVIEN can now be accessed by Australian patients, following on from its approval in other key healthcare markets, including the United States, Europe and Canada,” he said.

STA will seek to have ILUVIEN reimbursed via the Pharmaceutical Benefits Scheme.

Ends.

About Specialised Therapeutics Asia

Specialised Therapeutics is an international biopharmaceutical company established to commercialise new therapies and technologies to patients throughout Australia as well as in New Zealand and South East Asia.

ST 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.

About ILUVIEN

ILUVIEN (fluocinolone acetonide intravitreal implant) delivers 0.19 mg

fluocinolone acetonide via a sustained release intravitreal implant indicated to treat vision impairment associated with chronic DME considered insufficiently responsive to available therapies. Each ILUVIEN implant with its continuous microdosing delivery is designed to release submicrogram levels of fluocinolone acetonide, a corticosteroid, for 36 months, enabling the physician to treat this persistent disease consistently every day. ILUVIEN is contraindicated in the presence of pre-existing glaucoma or active or suspected ocular or periocular infection. The most frequently reported adverse drug reactions included cataract operation, cataract and increased intraocular pressure. www.ILUVIEN.com

About Diabetic Macular Oedema (DME)

DME, the primary cause of vision loss associated with diabetic retinopathy, is a disease affecting the macula, the part of the retina responsible for central vision. Diabetic retinopathy causes swelling in the macula due to blood vessel leakage, which leads to DME. The onset of DME is painless and may go unreported by the patient until it manifests with the blurring of central vision or acute vision loss. The severity of this blurring may range from mild to profound loss of vision.

About Alimera Sciences, Inc.

Alimera, founded in June 2003, is a pharmaceutical company that specializes in the commercialization and development of prescription ophthalmic pharmaceuticals. Alimera is presently focused on diseases affecting the back of the eye, or retina, because these diseases are not well treated with current therapies and will affect millions of people in our aging populations. For more information, please visit www.alimerasciences.com.

Further Inquiries

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Collaborate: We Work Closely with Global Business Partners



Collaborate: We work closely with our global business partners and take care of their products as if they were our own. We also manage complex regulatory landscapes in our regions. Here's Ulrich Kosciessa from photonamic GmbH discussing our successful partnership.

Click on the image above to view.

World First: AU Patients First to

Access Drug Developed from Sea Squirt

The following news clip appeared on National Nine News. Click on the thumbnail to view.



Channel 9 News: June 2019

The following news clip appeared on National Nine News. Click to view.



Specialised Therapeutics Asia Unveils ‘Track and Trace’ Pharma Model to Boost Drug Security, Improve Patient Safety

Singapore, 17 May 2019: Independent pharmaceutical company Specialised Therapeutics Asia (STA) is launching an innovative tracking system that will enable real time monitoring of every unit of drug product provided through its supply chain - from packing to patient.

The company, which markets specialist medicines to patients in Australia, New Zealand and across South East Asia, has adopted a model called the Unique Product Identification (UPI) system, that will see a unique 2D barcode printed on every drug product packaged and distributed by the company.

Current batches of two new products supplied by STA - NERLYNX[®] (neratinib) for breast cancer and APLIDIN[®] (plitidepsin) for multiple myeloma - are the first to be coded using this sophisticated technology. The UPI system is expected to be rolled out across the company’s entire portfolio by 2020.

STA is an early pharmaceutical adopter of this tracking model in this region, which is mandated in both the United States and Europe. It is designed to improve product integrity by minimising or eliminating dispensing errors, as well as eliminate the potential for counterfeit products to enter the legitimate pharmaceutical supply chain.

Chief Executive Officer Mr Carlo Montagner said the company's UPI technology was "predominantly about ensuring international best practice is employed in terms of drug security and patient safety".

"Track and trace technologies enable us and our partners to ensure safe drug distribution chains, and to implement any product recalls as rapidly as possible," Mr Montagner said.

"In the event of an urgent product recall, we can now quickly and effectively track every unit of product to ensure patient safety remains paramount."

Mr Montagner said it was common practice for pharmacy compounders to package intravenous cancer drugs for individual patients from multiple supply batches in order to minimise wastage.

"Without tracking technology, there has been poor visibility on the final destination of all batches produced," he said.

"Our new UPI model will ensure that we know exactly which vial any single patient has received from which batch. If there is a recall or any other problem, we can track every unit of product to the patient."

Mr Montagner said it was inevitable a Federal Government-mandated tracing system would be implemented industry-wide given the practice is now mandated in the EU and US.

"I would call on the Federal Government and indeed, all pharmaceutical manufacturers to introduce similar measures to ensure the highest patient safety standards are adopted," he said.

"We are proud to be Australian innovators but believe these measures must be widely adopted by all pharma companies in this region to mitigate potential patient risks."

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.

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Pharma in Focus: 17 May, 2019

PHARMA IN FOCUS

By Megan Brodie 17 May 2019

Drugs to be Tracked End-to-End

Local pharma Specialised Therapeutics Australia (STA) has launched a tracking system that will enable real time monitoring of its drug products as they move through the supply chain, while also making the practice of vial sharing more difficult.

The company has adopted a Unique Product Identification (UPI) system that involves printing a 2D barcode on every drug product packaged and distributed, beginning with STA's newest cancer drugs Nerlynx and Aplidin.

While the drugs have been registered by the TGA in the past six months, they are not yet listed on the PBS. Nerlynx was rejected by the PBAC in March and Aplidin is to be considered by the committee in July.

"The UPI system is expected to be rolled out across the company's entire portfolio by 2020," STA CEO Carlo Montagner said, describing his company as "an early pharmaceutical adopter" of the tracking system which is mandated in the US and Europe.

Montagner said the tracking system was designed to improve product integrity by minimising or eliminating dispensing errors and the chance of counterfeit products entering the supply chain, he said it would also prevent the vial sharing practice used in hospital pharmacies to prevent product wastage and save costs.

Montagner said it was common practice for pharmacy compounders to package intravenous cancer drugs for individual patients from multiple supply batches in order to minimise wastage, yet companies were paid per patient not by volume.

With 80 per cent of STA's cancer drugs used in a hospital setting, Montagner told Pharma in Focus this week the practice of vial sharing was a significant threat to both the company's earnings and patient safety because the vial used could not be identified.

"Without tracking technology, there has been poor visibility on the final destination of all batches produced," he said.

"Our new UPI model will ensure that we know exactly which vial any single patient has received from which batch. If there is a recall or any other problem,

we can track every unit of product to the patient.”

Montagner said it was inevitable a drug tracking system would be implemented industry-wide under federal government mandate in line with Europe and the US.

“I would call on the federal government and indeed, all pharmaceutical manufacturers to introduce similar measures to ensure the highest patient safety standards are adopted,” Montagner said.

“We are proud to be Australian innovators but believe these measures must be widely adopted by all pharma companies in this region to mitigate potential patient risks.

“Track and trace technologies enable us and our partners to ensure safe drug distribution chains, and to implement any product recalls as rapidly as possible. In the event of an urgent product recall, we can now quickly and effectively track every unit of product to ensure patient safety remains paramount.”

Pharma in Focus: 14 May, 2019

PHARMA IN FOCUS

By Megan Brodie 14 May 2019

PBAC System Labelled ‘Broken’

Australia’s reimbursement process for listing new drugs is broken and Australia is now on the precipice of missing out on new drugs, Specialised Therapeutics Australia CEO Carlo Montagner has warned.

Companies spend millions of dollars and take years to get a new drug listed on

the PBS, says Montagner, yet the system is not designed to handle complex new therapies, which include most cancer drugs.

“The system is broken,” Montagner, who is also the owner of STA, told Pharma in Focus. “Patients are denied access to new drugs sometimes for years as we try to understand what is required.”

With STA’s new breast cancer drug Nerlynx rejected by the PBAC in March and the company’s newest therapy Aplidin to be considered by PBAC in July, Montagner says these high cost new drugs face rejection at least once if not twice due to a failure in the PBAC evaluation process.

A meeting with PBAC chair Andrew Wilson following the rejection of Nerlynx highlighted the problem for Montagner, who said the committee had legitimate concerns which could have been addressed in the submission had the company known.

However, with pre-PBAC submission meetings held with the department of health, he said PBAC did not see Nerlynx before its March meeting and STA remained unaware of its concerns until the submission was rejected.

“There was a lack of understanding as to where [Nerlynx] had a place in therapy,” he said. “The TGA, FDA and EMA had all agreed on the analysis but the PBAC did not.

“If we had the opportunity to hear these questions, we could have addressed them and I think they would have been satisfied with the responses. Instead we now have to reapply.”

The issues must now be addressed in a resubmission which cannot be heard before November.

“It’s frustrating we can’t have a dialogue with the PBAC prior to its meeting,” he said. “We don’t have any discussions with the committee as to what it requires until the drug is rejected.”

Montagner told Wilson Australia needed a model similar to the US system whereby an oncology committee considers an application for market access prior to FDA consideration.

He is now planning to meet with the incoming health minister after the election to relay his concerns regarding both PBAC and the need for greater harmonisation between the MSAC and PBAC processes. STA is currently on its seventh submission for its genome analysis product Oncotype DX.

“The key to cancer care is around diagnostics and the current National Medicines Policy is not designed for this,” he said. “It needs to adjust and to adjust quickly.”

Montagner warned Australia was “on the precipice of missing out on drugs” with rebates the only reason many companies accepted what were either among the lowest or the lowest price in the world for new therapies.

He said delays in access also needed to be addressed with first time major submissions taking on average two to three meetings before being positively recommended, and patients waiting years for new therapies.

“With Aplidin, patients don’t have two to three years to wait,” he said. “Patients are dying within six to nine months.”

STA successfully launched two cancer drugs onto the PBS under the Coalition but invariably battled its way through PBAC.

Chemotherapy nausea drug Akynzeo was twice rejected before being listed in April 2016 and cancer drug Abraxane was rejected for breast cancer in 2015 before being resubmitted in breast and pancreatic cancer to the March 2019 meeting where it was positively recommended.

Mother’s Day



On Mother's Day 2019 we recognise the Mothers and Daughters who face a breast cancer diagnosis together. Janet and Julie Kesby have both been diagnosed twice and have supported each other all the way. Both are well at the moment and say their bond was always good; now it's unbreakable. They shared their stories with Specialised Therapeutics in May 2019.

Janet's Story:

"I am 78 years old. I have four children and I am retired. I was first diagnosed with breast cancer in 1991, when I had a right breast mastectomy. I did not need chemo because they caught it early, thank goodness. But then, in 1998 I was diagnosed again. This time it was in my left breast. Doctors told me the multiple cancer tumours were not even related to my first experience and that these episodes were entirely different. So, I then had a left breast mastectomy. I was fit

and healthy before both diagnoses, so I was in shock. Again, I did not have chemotherapy. I trusted the doctors who told me they had caught it early for a second time, but I took Tamoxifen as a preventative medication for a number of years. Both times I faced breast cancer, my daughter Julie was a great support. She even took long service leave and holidays to help me and my husband on our farm. I will never forget it. On the second diagnosis she again took leave and travelled from Canberra to Millbank (near Kempsey) to care for me.

I was devastated when Julie was diagnosed in 2009 because I knew exactly what she was feeling. But I also knew you could get through it - because I had. This time it was my turn to help. I travelled to Canberra to be with Julie, and her sister Alison.

When Julie was diagnosed for a second time (in 2014), her sister was her main support because I was at home supporting my husband on the farm.

Our bond is strong and we are the best of friends. Coping with cancer has probably made us closer. We have a common interest in dragon boat racing and we really understand the process of coping with cancer. We think we are both okay for now.

There have been silver linings from this whole experience. I was a migraine sufferer and I have not had one since 1991. Maybe it was the hormones?

I received wonderful support from family and friends, and also from sporting friends each time I was diagnosed.

I faced another cancer battle in 2007 when I was diagnosed with rectal cancer. This involved major surgery and chemotherapy, but I have come through everything again.

Julie has always been a great support. We are similar in that we both have faith and we believe in prayer. We encourage each other to be positive and each time we have been diagnosed, we have worked really hard to get back on track and return to normal activities.

How would I describe the mother daughter bond? Unbreakable. We have been there in good times and bad. As a mother, I am grateful to her for all she has done for me. And I hope she has always been able to rely on me."

Julie's Story:

"I am 55 years old and am retired at present, but I am looking to work again. I was a Research Officer for 29 years at the University of New South Wales in Canberra, before being made redundant in 2016.

My first diagnosis was in 2009 when doctors found abnormal cells inside one of the milk ducts in my right breast. I then undertook two wide incisions before a mastectomy in January 2010. Then I was diagnosed again in 2014. It was April Fool's Day when the GP confirmed the results that I had two tumours in my left breast. I could not believe it was back, and undertook the mastectomy of my left breast and removal of lymph nodes. No chemo was required. I have just finished the five years of Tamoxifen post-surgery.

I was in shock at the first diagnosis, but looking back, I had been fatigued. I put this down to work and life but there was obviously something else going on. I could not believe it when I was diagnosed again when I was very fit and back to life in full swing.

I got through both times by keeping myself really fit, dragon boat racing and playing tennis.

I did have great support from family and friends each time. And I had confidence in the medical teams and in my wider support network.

My Mum was a great example of determination. Her drive to recover from her breast cancer inspired me. She gave me great strength to get through everything and understand the steps to recovery.

How would I sum her up? My Mum is inspirational! Having said that, my Dad, sisters and brother and families have also given me great support and great love along the way. Dad has been a great carer to Mum and a very special support to us both. Mum, Dad, Alison and I have celebrated together milestones through some special family overseas trips to Canada, USA and UK. More recently Mum

and my sister Alison travelled to Italy and Switzerland.

Mum and I do have a special understanding of each other because of what we have gone through. Our common interest in dragon boat racing (through Flamin' Dragons, Aussie Dragonflies and Dragons Abreast Canberra teams) and tennis has also strengthened this bond.

We are close, tight and true friends, as well as Mother and Daughter. Mum understands me when I'm celebrating and consoles me when I am down.

We are both well at the moment. I am determined to stay fit and healthy and to keep travelling. I also want to continue my volunteer work and mentoring of others.

Mother's Day has always been a celebration of our Mum and past Grandmas. This year will be no different."

*May 2019.