Specialised Therapeutics Strikes Deal with World Courier Australia to Manage Logistics for Specialty Pharma Products

Melbourne, Australia 16 June 2016: International biopharmaceutical company Specialised Therapeutics Australia has struck an important agreement with global logistics partner World Courier Australia (WCA) to manage and handle its growing portfolio of specialist healthcare products around the country.

Herald Sun: 8 April, 2016

HERALD SUN (MELBOURNE)

By Carlo Montagner 8 April 2016

PBS Price Cuts Cruel Pharma Innovation

Earlier this week, pharmaceutical companies across the country received a substantial financial penalty, as the federal government's Pharmaceutical Benefits Scheme cost-saving agenda took effect.

Under this plan, expected to save the government around $3.7 billion over the next five years, all branded medicines listed on the PBS for five years or more will be available to the government at 5 per cent less than the originally agreed reimbursed price.

While taxpayers will see a difference in the price of many high-volume generics under this plan, the 5 per cent price reduction to prescribed specialty branded medicines will not result in taxpayers seeing any difference at the pharmacy counter.

That's because a patient's co-payment will remain the same regardless of what the government pays for the specialty medicine.

This decision will affect dozens of branded medicines and almost every pharmaceutical company in Australia. A 5 per cent price cut might seem insignificant, but in reality it will potentially slash millions of dollars from some companies' bottom lines.

Australia's pharma industry invests over $1 billion every year in health and medical research, exports billions in manufactured goods and indirectly employs around 20,000 Australians. But behind the scenes, and what many Australians don't realise, is that pharmaceutical companies are innovators, educators and philanthropists. They consistently fund clinical trials of new drugs that may change lives, educate the medical community about new technologies and provide millions of dollars in financial support to health programs.

Pharmaceutical companies also frequently support extensive compassionate programs enabling patients access to specialty medicines — not yet approved or reimbursed on the PBS — that might otherwise be unaffordable or unavailable. Not every drug makes it to market. For every innovative therapy that changes lives, there are hundreds that fail — in some cases, after many millions of dollars have been spent by pharma companies in development. This is not a waste. Many a brilliant discovery was made on the back of supposed failures. The reality is innovation is risk-laden, and the financial investment required is not for the faint-hearted.

Everyone I have worked with at global pharmaceutical companies, from lab researchers to senior executives, is striving to make a difference. They constantly balance the need for commercial viability against a genuine drive to innovate and bring new life-saving medicines and technologies to their communities. So while positive for the federal Budget, these latest PBS cost-saving measures pose an unprecedented commercial challenge for innovator pharma companies.

The prices of many drugs in Australia were originally negotiated at levels that

result in some of the lowest prices in the world. Further, the opportunity to increase prices once a drug has been listed on the PBS is virtually non-existent. We wear the costs of any manufacturing price rises or any significant currency devaluations from the time a drug is listed — unlike private health insurers, for example, who are accustomed to achieving increases in excess of CPI each year. It is vital the risk companies take on behalf of all patients is financially supported.

This is the first forced price cut introduced by the government — we don't know if it will be the last. If prices are further reduced, there is a real possibility pharma companies will remove some specialty branded medicines from the PBS because it will not be commercially viable given the current pricing.

If this happens, cuttingedge, life-saving drug therapies currently listed and being used to treat Australian patients may become unavailable and future breakthrough treatments may never be brought to Australia.

There is little doubt PBS pricing changes will impact innovation. Pharma companies will simply not have the same commercial incentive to include Australian sites in global studies of new drugs and technologies. I was relieved and emboldened by the Prime Minister's Innovation Statement. However, the reality is that to remain competitive and progressive, the pharmaceutical industry must be incentivised to continue investing in Australia. I ask the government to remember its commitment to innovation.

Novel Multiple Myeloma Drug APLIDIN® Shows Positive Results

in Pivotal Phase 3 Study

Singapore, Madrid and Melbourne, Australia, 31 March 2016: International biopharmaceutical company Specialised Therapeutics Asia Pte Ltd (ST Asia) will seek regulatory approvals for novel multiple myeloma drug Aplidin® (plitidepsin) following the release of positive results in a pivotal Phase 3 study.

From Big Pharma to Small Starts: Risking it All on a Life-Saving Cancer Drug to Win

SARAH-JANE TASKER | THE AUSTRALIAN| MARCH 19, 2016 12:00AM

From Big Pharma to Small Starts: Risking it All on a Life-Saving Cancer Drug to Win

Bozena Zembrzuski and Carlo Montagner reflect on their decision to found Specialised Therapeutics and bring Abraxane to Australia. Picture: Aaron Francis

After years working for big pharma in the US, Carlo Montagner and Bozena Zembrzuski risked their life savings to bring a leading cancer drug to Australia.

The two, who met at university, sold everything almost eight years ago — share portfolios and investment properties — and lived in rented accommodation when they returned to Australia to start their own pharmaceutical company, Specialised Therapeutics.

Montagner, who became chief executive, says he and his wife — parents to three children — took a risk on the Melbourne start-up. The early days of the business were a stark reminder of these risks.

The first drug they wanted to bring into Australia, Abraxane, developed to treat breast cancer, was originally rejected by the Pharmaceutical Benefits Scheme — the system under which the government subsidises the cost of medicine.

“I called my wife after I was told the PBS had rejected it and her first words were ‘we’re — ruined’,” Montagner says.

“I said we weren’t because ‘it is too good a drug not to get through, so let’s play it

through'."

The couple, like most Australians, have watched friends and family battle cancer. Montagner's father died last September from mesothelioma and the oncology expert says that, given his role, he is often approached by friends and family for advice on the deadly disease.

"When I receive a call from a friend for advice, it's usually not for financial advice, so I generally tense up," he says.

"For most patients given cancer diagnosis, and I went through this myself with my father last year, it's just mind numbing, you don't know where to turn and there's a lot of information out there," Montagner says.

The privately owned company — Montagner has no interest in attracting third-party investors — generated more than $35 million in revenue last year but he says it isn't just about money.

"I'm very passionate about this. I really do believe that this (Abraxane) is the chemotherapy that all Australian women should receive."

Bringing a drug to the Australian market is usually reserved for those with deep pockets and time on their side. Drugs have to be licensed, which involves significant testing to secure the right local approvals. The testing needs to be done regardless of a drug's use or approval in other jurisdictions.

Montagner tells The Weekend Australian the original financial risk they took as a family was worth it because he had a strong belief in Abraxane, which he had launched in the US in his previous role as president of the drug's developer, Abraxis Bioscience.

Prior to the introduction of that drug into Australia in 2009, Montagner said breast cancer patients were using older chemotherapies that had been around for 20 years.

He says that today, Abraxane is one of the leading therapies for metastatic breast cancer and pancreatic cancer. Since the drug became available in Australia, more than 10,000 cancer patients have been treated with Abraxane.

The drug, which is now owned by US pharma Celgene, has been approved for

distribution in about 50 countries, including the US, Europe, Japan and India.

Montagner says the early take-up of the drug in Australia had exceeded their expectations “several fold”.

“We got caught in the first 18 months never really having enough stock,” he says.

“I couldn’t believe how quickly it was being adopted. We put the manufacturing plant in Phoenix under pressure … the plant once pulled out all stops, working 24-7 for a week to make a batch for Australia because we were selling so much of it.”

Zembrzuski says while the company was started with some trepidation, they took the view that if it didn’t work, they would simply get jobs again.

“We had a lot of faith in all the training and experience we’d built up in our previous roles in Australia and overseas,” she says.

The company co-founder, who previously worked for global drug giant Novartis, says it’s a different dynamic to have a married couple as the bosses, which she said had the potential to go terribly wrong.

“We were very aware right from the start that being married should not cause any confusion or stress to people,” she says.

“If this was going to be a credible and professional venture then that couldn’t happen.”

Zembrzuski jokes that she was worried if she could take direction from her husband given he had taken on the CEO role. She says she decided to treat him at work as she would any of her previous managers.

“We both have strong opinions, are both self-motivated and have always worked for other people, never together,” she says. “But we bring different strengths to the table and we do complement each other.”

The company was originally started because Montagner says it was difficult to get a role in Australia that matched the remuneration he was accustomed to in the US as the president of a Nasdaq-listed biotech. He and his wife are passionate about conveying that they don’t take the success of the company for granted.

“We feel very lucky that we are able to provide for the kids and are our own bosses,” Zembrzuski says.

Teaching their three children, aged 9, 12 and 14, about giving and not just taking is central to the values they want to pass on as parents.

Montagner says that before they went to the US, they were like most Australians and saw people who sprouted philanthropic endeavours as “show-offs”.

“Then we went to the US and there it’s in the DNA of all successful people. We saw that and we completely changed our view and bought into the concept that people who do well and have the opportunity to give back should give back,” he says.

“Plus, we both grew up in working class families that didn’t have the opportunities to do what we do now, so the last thing we want is our kids to grow up in a privileged household where they became too materialistic and focused on themselves than others in greater need.”

The family started its philanthropic efforts with a $1m donation to the Olivia Newton-John cancer research centre based at Melbourne’s Austin Hospital. They have also donated $US250,000 ($328,000) to build a trade school in East Timor.

Zembrzuski adds they are a “proud” Australian-owned company and while they will always maintain their head office in Melbourne, part of being entrepreneurial was looking at new options.

They expanded into Southeast Asia last year with the distribution of a drug to treat myeloma, a type of blood cancer.
“We aim to bring drugs to Australia and South East Asia that fulfil unmet medical needs,” Montagner says.

“We say no to drugs that don’t provide a unique benefit because then it becomes a pure marketing exercise if it doesn’t and we’re not interested in that.”

The company was founded on oncology drugs but it is also targeting haematology, urology and supportive care.

The rapid growth of Specialised Therapeutics has put it on the radar of larger companies but Montagner says he has no plans to sell.

“I love the fact we’re in a position where we can help others with some of the wealth we are generating and I love coming to the office each day and doing what we do. I see Rupert Murdoch and Warren Buffett … what I take from them is they love what they do, it’s not a job, it’s what you do every day.”

The Australian: 19 March, 2016

THE AUSTRALIAN

By Sarah-Jane Tasker 19 March 2016

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Specialized Therapeutics Grants Sublicense for Anti-Emetic Products to Mundipharma for Australia and New Zealand Anti-emetic Products Covered Under the Sublicense Agreement Include ALOXI® (palonosetron hydrochloride) and AKYNZEO® (netupitant/palonosetron).

Melbourne, Australia, 7 March 2016: Specialized Therapeutics Pty Ltd and Mundipharma Pty Limited today announce a sublicense agreement enabling Mundipharma to assume all commercialisation responsibilities for the anti-emetic products ALOXI® (palonosetron hydrochloride) and AKYNZEO® (netupitant/palonesetron).

Under the terms of the arrangement, Specialized Therapeutics grants Mundipharma exclusive marketing, promotion, distribution and sales rights for the anti-nausea and vomiting pharmaceutical products ALOXI® and AKYNZEO® in Australia and New Zealand markets.

ALOXI® is indicated for the prevention of acute nausea and vomiting associated with chemotherapy[1] and has been commercially available in Australia since 2010 under license from Helsinn Healthcare SA, a Swiss pharmaceutical company which has consented to the sublicense agreement.

AKYNZEO® is the first fixed combination oral agent targeting two critical signalling pathways associated with chemotherapy induced nausea and vomiting (CINV) by combining netupitant, an NK1 receptor antagonist, and palonosetron, a 5-HT_3 receptor antagonist, in a single capsule.[2]

AKYNZEO® is also supplied by Helsinn, and was approved by Australia's Therapeutic Goods Administration in May 2015. A submission for reimbursement on the Pharmaceutical Benefits Scheme (PBS) was submitted in 2015 and is nearing completion.

About ALOXI® (palonosetron hydrochloride)

ALOXI® (palonosetron hydrochloride) is a second generation 5-HT_3 receptor antagonist, developed for the prevention of chemotherapy-induced nausea and vomiting (CINV) in patients with cancer, with a long half-life of 40 hours. ALOXI® has been developed by the Helsinn Group in Switzerland and today it is marketed as Aloxi®, Onicit® and Paloxi® in more than 50 countries worldwide. In Australia, Aloxi® is PBS listed for the management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.[3]

For more information about ALOXI®, please visit the website: www.aloxi.com

About AKYNZEO® (netupitant/palonosetron)

AKYNZEO® is an oral, fixed combination of an NK1 receptor antagonist, netupitant, and a 5-HT_3 receptor antagonist, palonosetron, in a single capsule, that targets two critical signalling pathways associated with chemotherapy-induced nausea and vomiting (CINV).[2]

AKYNZEO® was approved by the US Food and Drug Administration (FDA) in October 2014 and by the European Commission in May 2015. In Australia, AKYNZEO® was approved by the Therapeutic Goods Administration in May 2015. It is indicated in adult patients for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy and for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.[2] An application to New Zealand's regulatory authority MEDSAFE has been submitted and is under review. Additional regulatory submissions for netupitant/palonosetron fixed combination are underway worldwide.

About Specialized Therapeutics Pty Ltd

Specialized Therapeutics Pty Ltd, a wholly owned subsidiary of Specialised Therapeutics Australia Pty Ltd, is a biopharmaceutical company dedicated to working with leading international pharmaceutical companies to provide patient access to innovative healthcare solutions.

For more information, please visit www.specialisedtherapeutics.com.au.

About the Helsinn Group

Helsinn is a privately owned cancer supportive care pharmaceutical group with

an extensive portfolio of marketed products and a broad development pipeline. Since 1976, Helsinn has been improving the everyday lives of patients, guided by core family values of respect, integrity and quality, through a unique integrated licensing business model working with long standing partners in pharmaceuticals, medical devices and nutritional supplement products. Helsinn is headquartered in Lugano, Switzerland, with operating subsidiaries in Ireland and the US (Helsinn Therapeutics), a representative office in China, as well as a product presence in about 90 countries globally.

For more information, please visit www.helsinn.com.

About Mundipharma

Mundipharma's global network of companies are privately owned entities covering the world's pharmaceutical markets. Mundipharma provides patients across 6 continents with a growing portfolio of 19 products in 5 therapeutic areas, which include moderate-to-severe pain, consumer healthcare, oncology, respiratory disease, rheumatoid arthritis, antiseptics and laxatives. Mundipharma is a prime example of a company that consistently delivers high quality products while standing by the values that represent the company. Our mission is to alleviate the suffering of patients and to substantially improve their quality of life.

For more information, please visit: www.mundipharma.com.au

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2. AKYNZEO® Approved Product Information available at: http://www.specialisedtherapeutics.com.au/assets/files/d-akynzeo_pi.pdf
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Specialised Therapeutics Asia to Distribute Novel Multiple Myeloma Drug APLIDIN® in South East Asia, Australia and New Zealand

SINGAPORE and MELBOURNE, Australia, Feb. 2, 2016 /PRNewswire/ — International biopharmaceutical company Specialised Therapeutics Asia (ST Asia) will supply and distribute a novel oncology drug candidate throughout South East Asia, following an exclusive licensing deal with European pharmaceutical company PharmaMar.

Under the terms of the latest agreement, ST Asia will be allowed marketing and distribution rights to new multiple myeloma compound APLIDIN® (plitidepsin) in key regions including Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Papua New Guinea, Philippines, Singapore, Timor-Leste, Thailand, and Vietnam, as well as in Australia and New Zealand.

APLIDIN is a first in class drug currently in development for the treatment of multiple myeloma and a type of T cell lymphoma.

Commercial terms of the agreement are not being disclosed, but PharmaMar will receive an upfront payment, royalties and additional remunerations for regulatory and sales milestones achieved by APLIDIN in these new markets.

PharmaMar will retain production rights and will supply the finished product to ST Asia for exclusive
commercial use in all agreed regions.

APLIDIN is PharmaMar's second anti-cancer drug candidate obtained from a marine organism. The company announced in June 2015 that patient recruitment of the international pivotal Phase 3 trial (ADMYRE) for APLIDIN in

refractory/relapsed multiple myeloma was successfully completed.[1] Data from this study is expected to be reported later this year.

Specialised Therapeutics Asia Chief Executive Officer Mr Carlo Montagner said the APLIDIN licensing deal was an important step forward as the company expanded operations to include key territories in South East Asia.

“We look forward to working with PharmaMar to ensure this valuable multiple myeloma therapy is available as soon as possible to patients in key South East Asia regions, as well as in Australia and New Zealand,” he said.

“APLIDIN may be highly valuable as a new therapeutic for this difficult to treat cancer. While multiple myeloma remains relatively rare, it is an insidious disease with one of the lowest survival rates in oncology. ST Asia has been established to provide new therapeutics like this one to patients where there is a high unmet need.”

“APLIDIN is the first step. We look forward to changing the lives of patients affected by a range of diseases – not only in oncology – in these new and important markets.”

PharmaMar Chairman José María Fernandez Sousa-Faro said: “We are proud to enter into agreements with laboratories such as STA that enable us to ensure that all patients who need plitidepsin can avail themselves of it. We are firmly committed to advancing in the development of innovative therapies that benefit society.”

The total population of South East Asian regions including Australia and New Zealand is put at 650 million, with an estimated 300,000 people living with multiple myeloma overall and between 30,000 and 40,000 new cases of the disease diagnosed annually.

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. The company is a close affiliate of Specialised Therapeutics Australia (STA), which also collaborates 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, with a broad therapeutic portfolio spanning oncology, hematology, urology and ophthalmology. Additional information can be found at www.specialisedtherapeutics.com.au.

About PharmaMar

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

About APLIDIN® (plitidepsin)

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

triple combination of plitidepsin, bortezomib and dexamethasone, and a Phase II study in relapsed or refractory angioimmunoblastic T-cell lymphoma. Plitidepsin has received orphan drug designation by the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA).

About multiple myeloma

Multiple myeloma is a relatively uncommon type of blood cancer that accounts for 10% of all hematological malignancies and that is caused by malignant plasma cells that very rapidly multiply.[2] Normal plasma cells are white blood cells found in the bone marrow that form part of the immune system and produce the antibodies necessary to fight infections.[3] Abnormal cells produce a type of antibody that does not benefit the body and accumulate, thus preventing normal cells from functioning properly.

Almost all patients with multiple myeloma progress from an initial, asymptomatic pre-malignant stage to established disease. In 2015, 26,850 new cases will be diagnosed in the US, and about 11,200 people will die of this disease.[4] In Europe, there will be 4.5–6.0 out of 100,000 people diagnosed per year.[5] In Australia, approximately 1,200 Australians are diagnosed each year.[6]

- APLIDIN® is a novel drug to treat multiple myeloma, which has one of the

lowest survival rates in oncology

- First major license deal for Specialised Therapeutics Asia – international biopharmaceutical company supplying novel oncology drug candidates to key SE Asia regions, as well as Australia and New Zealand
- Specialised Therapeutics Asia is new partner company of Specialised Therapeutics Australia

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   SOURCE Specialised Therapeutics Asia

Channel 10 News: November 2015

The following story appeared on Channel 10 News nationally following a PBS listing. Click to view.

Channel 9 News: November 2015

The following story appeared on Channel 9 News nationally following a PBS listing. Click to view.

Channel 7 News: November 2015

The following story appeared on Channel 7 News nationally following a PBS listing. Click to view.


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