

New Therapy to Treat Advanced Small Cell Lung Cancer ZEPZELCA[®] (lurbinectedin) Approved in Singapore

Singapore, 22 September 2021: SINGAPORE patients with an aggressive form of lung cancer (metastatic small cell lung cancer) can now access a new therapy that may improve outcomes.

The drug ZEPZELCA (lurbinectedin) has been provisionally approved by Singapore's Health Sciences Authority (HSA) **"for the treatment of adult patients with metastatic small cell lung cancer (SCLC) who have progressed after prior platinum-containing chemotherapy"**.¹

This means patients who have failed other existing treatment options will now have a further therapeutic option.

ZEPZELCA is the first new therapy approved by the HSA to treat second-line SCLC in more than two decades, and is the third oncology drug in Specialised Therapeutics (ST) portfolio to receive HSA approval.

The Singapore approval follows on from approvals by the US Food and Drug Administration (FDA) decision², as well as the Therapeutic Goods Administration (TGA) in Australia.³

"The new availability of ZEPZELCA will be welcomed by patients, families and the medical community, as we strive to improve patient outcomes for this disease," Professor Mitchell said.

"With this approval, we now have another option for patients who have progressed after prior platinum-based treatments. This provides an opportunity for them to continue treatment and potentially, improve outcomes."

The HSA approval of ZEPZELCA has been granted following collaboration with the US FDA via the 'Project Orbis' initiative, due to the high unmet clinical need

in SCLC. It is based on monotherapy clinical data from an open-label, multi-centre, single-arm study in 105 adult platinum-sensitive and platinum-resistant patients with SCLC who had disease progression after treatment with platinum-based chemotherapy.⁶

The data, which appeared in *The Lancet Oncology* May 2020 issue, demonstrated that in patients with relapsed SCLC, ZEPZELCA provided an ORR of 35% and a median duration of response of 5.3 months as measured by investigator assessment (30% and 5.1 months respectively, as measured by an independent review committee (IRC)).⁶

The provisional approval is the subject of a further confirmatory study in more than 700 patients with 2L SCLC. This study is expected to be completed in 2025.

ZEPZELCA is being made available in Singapore by independent pharmaceutical company Specialised Therapeutics under exclusive license from its international partner PharmaMar.

Specialised Therapeutics Chief Executive Officer Mr Carlo Montagner said lung cancer was the third most common cancer in Singapore, representing more than 22% of all cancer deaths. SCLC represented between 10 – 15% per cent of all lung cancer diagnoses.^{7,8}

“We are delighted to be able to provide a new therapy option in Singapore for patients with this difficult to treat cancer,” he said.

“While patients may initially respond to traditional chemotherapy, they often experience an aggressive recurrence that is historically resistant to treatment.

“We expect that this therapy may now be an option for up to 100 Singapore patients every year and look forward to making a difference for these patients and their families.”

PharmaMar president José María Fernández Sousa-Faro, PhD, said the company was delighted South-East Asian patients would now be provided access to ZEPZELCA.

“We are pleased to bring a new treatment choice to relapsed SCLC patients. “The accelerated approval of ZEPZELCA underscores its potential to fill an unmet

need in this often-overlooked SCLC community.”

ZEPZELCA has been available in Singapore via an Early Access Program since July 2020.

Ends.

About SCLC in Singapore

SCLC represents a serious condition. It is a particularly aggressive type of lung cancer related to smoking that represents approximately 10-15% of all lung cancers, accounting for more than 275,000 new cases worldwide every year.^{9,10} SCLC is characterised by rapid growth, early dissemination that is often asymptomatic and with acquired resistance to drugs. SCLC is staged into limited-stage or extensive-stage disease. Limited-stage disease is potentially curable with aggressive therapy consisting of concurrent chemoradiotherapy, prophylactic cranial irradiation, and occasionally, surgery.^{11,12} However, nearly two-thirds of SCLC patients have extensive-stage disease at diagnosis, which is not curable, and patients are treated with palliative intent, with a median survival of 7 to 11 months after diagnosis and with less than 5% survival at 2 years.^{13,14}

Lung cancer is the third most common cancer in Singapore and represents 22.3% of all cancer deaths. Between 2014 and 2018, approximately 7,945 new cases of lung cancer were diagnosed in Singapore, with 10-15% of these classified as SCLC (between 150 and 240 new SCLC cases annually).^{7,8} While the age-standardised incidence rate of all lung cancer has been in decline since the 1970's (mid-50's per 100,000 in 1968 to mid-30's per 100,000 in 2017), the five-year relative survival has seen a moderate increase to approximately 10% in 2017. Globally, the prognosis of patients with SCLC is dismal with a 5-year survival rate of less than 5% and an average overall survival period of only 2-4 months for patients not receiving any active treatment.^{11,12}

Modern studies, including those of recent immunotherapies, suggest that between 40-60% of patients that receive front-line therapy will be clinically

eligible for second-line therapy.¹⁵⁻¹⁸ This suggests that, based on 2014-2018 lung cancer incidence figures from the Singapore Cancer registry⁸, between 60 to 100 patients would be eligible for second-line SCLC treatment in Singapore.

About ZEPZELCA[®] (lurbinectedin)

ZEPZELCA is an alkylating drug that binds guanine residues within DNA. This triggers a cascade of events that can affect the activity of DNA binding proteins, including some transcription factors, and DNA repair pathways, resulting in disruption of the cell cycle and eventual cell death.¹

ZEPZELCA or injection 4 mg is a prescription medicine used to treat adults with a kind of lung cancer called small cell lung cancer (SCLC) that has spread to other parts of the body (metastatic) and who have received treatment with chemotherapy that contains platinum, and it did not work or is no longer working. ZEPZELCA is approved based on response rate and how long the response lasted. Additional studies will further evaluate the benefit of ZEPZELCA for this use.

About the Phase II Monotherapy Trial

The Phase 2 trial of ZEPZELCA was an open-label, single-arm study, which enrolled a total of 105 SCLC patients at 26 hospitals in six European countries and the U.S.⁶ In the trial, platinum-sensitive and platinum-resistant patients were treated with ZEPZELCA 3.2 mg/m², administered as a 60-minute IV infusion repeated every 21 days until disease progression or unacceptable toxicity. The primary endpoint, ORR, was 35% and the median duration of response was 5.3 months as measured by investigator assessment (30% and 5.1 months respectively, as measured by an IRC).⁶ ZEPZELCA was discontinued in 1.9% of patients and was delayed in 30.5% of patients due to an adverse reaction. Dose reductions for an adverse reaction occurred in 25% of patients.⁶

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

About PharmaMar

Headquartered in Madrid, PharmaMar is a biopharmaceutical company, focused on oncology and committed to research and development which takes its inspiration from the sea to discover molecules with antitumor activity. It is a company that seeks innovative products to provide healthcare professionals with new tools to treat cancer. Its commitment to patients and to research has made it one of the world leaders in the discovery of antitumor drugs of marine origin.

PharmaMar has a pipeline of drug candidates and a robust R&D oncology program. It develops and commercializes YONDELIS® in Europe and has other clinical-stage programs under development for several types of solid cancers: lurbinectedin (PM1183), PM184 and PM14. With subsidiaries in Germany, Italy, France, Switzerland, Belgium, Austria and the United States. PharmaMar wholly owns other companies: GENOMICA, a molecular diagnostics company; Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi). To learn more about PharmaMar, please visit us at www.pharmamar.com.

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Discussion & Questions From The Audience



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Timing	Question
00:00:00	1. For recurrent desmoids or non-resectable desmoid tumors, do you like to see sorafenib as a first line or do you like to see chemotherapy as a first line?
00:05:00	2. How do we monitor the neurocognitive effects of Avapritinib?
00:07:02	3. For retroperitoneal, dedifferentiated liposarcoma, how long does the disease-free interval have to be to propose reoperating at the time of recurrence?
00:09:03	4. How do you like to image such dedifferentiated liposarcomas to plan a surgical resection? Is it CT, is it MRI, is it some combination? Do you ever use FDG-PET?

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Q&A: Catching Up On Key

Concepts



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Timing	Question
00:01:15	1. After STRASS 1, the preoperative versus no preoperative radiotherapy for primary retroperitoneal sarcoma, the first-line treatment per the results of this trial is
00:04:30	2. According to the global, Europe, Asia, America, Consensus-Based Guideline 2020 for desmoid fibromatosis, the first-line strategy of managing a desmoid, apart from any patient with a complication is?

00:07:25	3. What is the main clinical feature of BCOR rearranged sarcomas?
00:09:33	4. What of the following statements is correct (with reference to WHO classification)?
00:12:55	5. Avapritinib was approved in 2020 for what type of sarcoma?
00:14:27	6. Which of the following is false about NTRK fusions?

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Part 4: Through The Oncologist's Eyes - George Demetri



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Part 3: What The Pathologist Focusses On - Angelo Paolo Dei Tos



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Part 2: From The Surgeon's Point Of View - Sylvie Bonvalot



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Part 1: Welcome & Introduction - George Demetri



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New Therapy to Treat Advanced Small Cell Lung Cancer Approved for Australian Patients

Singapore, 14 September 2021: AUSTRALIAN patients with an aggressive form of lung cancer (metastatic Small Cell Lung Cancer) can now access a new therapy that may improve outcomes.

The therapy, ZEPZELCA™ (lurbinectedin) has been approved by the Therapeutic Goods Administration (TGA) “for the treatment of patients with metastatic small cell lung cancer (SCLC) that has progressed on or after prior platinum-containing therapy”.¹

This means patients who have failed other existing treatment options will now be able to access another line of therapy.

ZEPZELCA is the first new therapy approved by the TGA to treat second-line SCLC in more than two decades.

Australian lung cancer oncologist Professor Paul Mitchell from the Olivia Newton-John Cancer and Wellness and Research Centre said SCLC was particularly aggressive and more than two-thirds of patients were diagnosed with extensive stage disease. He said fewer than 5% of these patients currently survived more than five years post diagnosis.^{3,4}

“The new availability of ZEPZELCA will be welcomed by patients, families and the medical community, as we strive to improve patient outcomes for this disease,” Professor Mitchell said.

“With this approval, we now have another option for patients who have progressed after prior platinum-based treatments. This provides an opportunity for them to continue treatment and potentially, improve outcomes.”

The TGA approval of ZEPZELCA has been granted under a provisional regulatory pathway. The US Food and Drug Administration (FDA) and Australia's Therapeutic Goods Administration (TGA) collaborated via 'Project Orbis' to accelerate availability to Australian patients.

ZEPZELCA's approval is based on clinical data from an open-label, multi-centre, single-arm phase II study in 105 adult patients with SCLC who had disease progression after treatment with platinum-based chemotherapy.²

The data, which appeared in *The Lancet Oncology* May 2020 issue, demonstrated that in patients with relapsed SCLC, ZEPZELCA provided an Overall Response Rate (ORR) of 35% and a median duration of response of 5.3 months as measured by investigator assessment (30% and 5.1 months respectively, as measured by an independent review committee (IRC)).²

The provisional approval is the subject of a further confirmatory study in more than 700 patients with 2nd line SCLC including some Australian sites. This study is expected to be completed in 2025.

ZEPZELCA is being made available in Australia by the independent pharmaceutical Company, Specialised Therapeutics (ST), under exclusive license from international partner, PharmaMar.

ST Chief Executive Officer Mr Carlo Montagner said the approval of ZEPZELCA would potentially make a difference for around 400 Australian patients annually who had run out of treatment options.

"We are delighted to be able to provide a new therapy option for patients with this difficult to treat cancer," he said.

"While patients may initially respond to traditional chemotherapy, they often experience an aggressive recurrence that is historically resistant to treatment.

"Our mission has always been to provide therapies in areas of unmet need and SCLC is certainly one of these areas. We look forward to making a difference for these patients and their families."

PharmaMar president José María Fernández Sousa-Faro, PhD, said the Company was delighted Australian patients would now be provided access to ZEPZELCA.

“We are pleased to bring a new treatment choice to relapsed SCLC patients. “The accelerated approval of ZEPZELCA underscores its potential to fill an unmet need in this often-overlooked SCLC community.”

ZEPZELCA is currently available in Australia via a Special Access Program.

Commercial supplies of ZEPZELCA will commence early 2022.

Ends.

About Small Cell Lung Cancer (SCLC)

SCLC is a particularly aggressive type of lung cancer that represents approximately 10-15% of all lung cancers,³ accounting for more than 275,000 new cases worldwide every year. In Australia, around 1,900 patients are diagnosed annually with the disease,⁴ which is characterised by rapid growth, early dissemination that is often asymptomatic and with acquired resistance to drugs². SCLC is staged into limited-stage or extensive-stage disease. Limited-stage disease is potentially curable with aggressive therapy consisting of concurrent chemoradiotherapy, prophylactic cranial irradiation, and occasionally, surgery. However, nearly two-thirds of SCLC patients have extensive-stage disease at diagnosis, which is not curable, and patients are currently treated with palliative intent, with a median survival of 7 to 11 months after diagnosis and with less than 5% survival at 2 years.^{5,6}

About ZEPZELCA™ (lurbinectedin)

ZEPZELCA also known as PM1183, is an alkylating drug that binds guanine residues within DNA. This triggers a cascade of events that can affect the activity of DNA binding proteins, including some transcription factors, and DNA repair pathways, resulting in disruption of the cell cycle and eventual cell death.¹

ZEPZELCA 4 mg is a prescription medicine used to treat adults with a kind of lung cancer called small cell lung cancer (SCLC) that has spread to other parts of

the body (metastatic) and who have received treatment with chemotherapy that contains platinum, and it did not work or is no longer working. ZEPZELCA is approved based on response rate and how long the response lasted. Additional studies will further evaluate the benefit of ZEPZELCA for this use.

About the Phase II Monotherapy Trial

The Phase II trial of ZEPZELCA was an open-label, single-arm study, which enrolled a total of 105 SCLC patients at 26 hospitals in six European countries and the U.S.² In the trial, platinum-sensitive and platinum-resistant patients were treated with ZEPZELCA 3.2 mg/m², administered as a 60-minute IV infusion repeated every 21 days until disease progression or unacceptable toxicity. The primary endpoint, ORR, was 35% and the median duration of response was 5.3 months as measured by investigator assessment (30% and 5.1 months respectively, as measured by an IRC).² Serious adverse reactions in ≥3% of patients included pneumonia, febrile neutropenia, neutropenia, respiratory tract infection, anaemia, dyspnoea, and thrombocytopenia. ZEPZELCA was discontinued in 1.9% of patients and was delayed in 30.5% of patients due to an adverse reaction. Dose reductions for an adverse reaction occurred in 25 percent of patients.²

About Specialised Therapeutics Asia

Headquartered in Singapore, Specialised Therapeutics Asia Pte Ltd (STA) is an international biopharmaceutical company established to commercialise new therapies and technologies to patients throughout South East Asia, as well as in Australia and New Zealand. STA and its regional affiliates collaborate with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life-changing healthcare solutions to patients affected by a range of diseases. Its mission is to provide therapies where there is an unmet need. The company's broad therapeutic portfolio currently includes novel agents in oncology, haematology, neurology, ophthalmology and supportive care. Additional information can be found at www.stbiopharma.com

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PharmaMar has a pipeline of drug candidates and a robust R&D oncology program. It develops and commercializes YONDELIS® in Europe and has other clinical-stage programs under development for several types of solid cancers: lurbinectedin (PM1183), PM184 and PM14. With subsidiaries in Germany, Italy, France, Switzerland, Belgium, Austria and the United States. PharmaMar wholly owns other companies: GENOMICA, a molecular diagnostics company; Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi). To learn more about PharmaMar, please visit us at www.pharmamar.com.

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Specialised Therapeutics to Relaunch GELCLAIR in Australia

Singapore and Melbourne, Australia, 4 April, 2017: Independent pharmaceutical company Specialised Therapeutics Asia (ST Asia) will today relaunch a product used to relieve the pain of oral mucositis, a condition that can affect cancer patients undergoing chemotherapy and/or radiotherapy.

GELCLAIR is a bio-adherent oral gel that works by creating a protective film in the mouth, providing durable relief for the painful mouth ulcers that characterise the condition, as well as improving a patient's ability to eat, drink, swallow and speak.¹⁻³

ST Asia will market and distribute the product under license from partner, Helsinn Healthcare SASwitzerland.

Chief Executive Officer Mr Carlo Montagner said GELCLAIR was a welcome inclusion to the company's expanding oncology and supportive care portfolio.

"This product has been available in Australia before, but has been in hiatus since 2015," he said.

"We know there is continued demand for this important supportive care product and we are delighted to make GELCLAIR available once more to patients suffering from oral mucositis in Australia."

Internationally regarded oral mucositis expert Professor Dorothy Keefe said the condition could be extremely debilitating, even leading to malnutrition in some cases, with 20 to 40% of patients receiving conventional chemotherapy affected, as well as up to 100% of patients receiving radiation therapy for head and neck cancer.⁴

“Pain in your mouth, or ulceration in your mouth, makes it hard to eat and to swallow,” Professor Keefe said.

“Both of these factors have an impact on quality of life and people can lose 5-10% of their body weight if they are badly affected. GELCLAIR provides a protective barrier that reduces the pain experienced by patients, which is an important part of oral mucositis management.”

Australian journalist and broadcaster Julie McCrossin suffered the debilitating effects of oral mucositis while undergoing treatment for oropharyngeal cancer. She described the damage inside her mouth as “catastrophic”.

“I would highly recommend GELCLAIR as a soothing, nurturing mouth treatment that helped me both physically and psychologically in my recovery, when I was suffering the pain and discomfort of treatment for throat cancer,” she said.

“With GELCLAIR, I actually felt it was helping me to start the road to recovery because I felt better. When you are going through weeks and weeks of trauma to your soft tissue, that is worth a million bucks.”

GELCLAIR is available without prescription. Ordering information is available at www.STAbiopharma.com/gelclair. GELCLAIR can be purchased online only at <http://www.chemistwarehouse.com.au> or <http://www.epharmacy.com.au>

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, neurology, urology and ophthalmology. Additional information can be found at www.STAbiopharma.com

About Gelclair

Gelclair® is a viscous oral gel for the management and relief of pain associated with oral lesions, particularly oral mucositis/stomatitis, which may be caused by chemotherapy or radiation therapy and irritation from oral surgery.¹ Gelclair® forms a protective coating over the oral mucosa which shields exposed or sensitised nerve endings from over-stimulation and provides oral pain relief.¹⁻³ It does not irritate or sting and is non-numbing.¹

About the Helsinn Group

Helsinn is a privately owned pharmaceutical group with an extensive portfolio of marketed cancer care 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. The Group works across pharmaceuticals, biotechnology, medical devices and nutritional supplements and has expertise in research, development, manufacture and the commercialization of therapeutic and supportive care products for cancer, pain and inflammation and gastroenterology. In 2016, Helsinn created the Helsinn Investment Fund to support early-stage investment opportunities in areas of unmet patient need. The company is headquartered in Lugano, Switzerland, with operating subsidiaries in Ireland and the US, a representative office in China as well as a product presence in about 90 countries globally. For more information, please visit www.helsinn.com.

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Specialised Therapeutics to Remove Territory Sales Incentives from Staff Bonus Plan

Melbourne, Australia, 1 February 2017: International biopharmaceutical company Specialised Therapeutics will today launch a new company business model, as part of a bold plan to improve relationships with healthcare professionals.

Under this plan, sales teams will no longer be paid bonuses based on the number of prescriptions written. Instead, in field representatives will be rewarded for demonstrated customer service excellence, as well as high level product and

disease knowledge.

Chief Executive Officer Carlo Montagner said similar sales models had been introduced by some of the world's most successful companies – including Apple and Tesla – with the focus on relationships and quality information exchange rather than a singular sales outcome focus.

“By removing the pressure of individual territory sales targets, we believe our team members can engage in more genuine and meaningful discussions with the healthcare professionals we are regularly interacting with, who at this stage are predominantly oncologists and haematologists,” he said.

“We believe that by doing business in this way, we will actually improve commercial outcomes, because it removes the ‘elephant in the room’ which is the sales message that can make both parties feel uncomfortable. This is simply a transparent and ethical way of doing business.”

ST is believed to be among the first pharmaceutical companies in the region to break away from the traditional pharmaceutical business model, which has long rewarded representatives with bonuses tied to the number of product prescriptions in their territories.

Mr Montagner added: “This model is about putting patients and the health care professionals we interact with first. It means our staff are a valuable resource across their therapeutic areas.

“Our in field liaison teams are wholeheartedly in favour of this new business model and we look forward to engaging with the medical community in a way that is transparent, genuine and meaningful as we move into 2017.”

About Specialised Therapeutics Asia

Specialised Therapeutics is an international biopharmaceutical company established to provide pioneering healthcare to patients throughout Australia, New Zealand and South East Asia. The company 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.

Specialised Therapeutics 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.STAbiopharma.com

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