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 drugs[2]. 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/m^2, 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

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.

Further Enquiries

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References:

1. ZEPZELCA (lurbinectedin) Australian Prescribing Information.
2. Trigo J, Subbiah V, Besse B, et al. Lurbinectedin as second-line treatment for patients with small-cell lung cancer: a single-arm, open-label, phase basket trial. Lancet Oncol. 2020 May;21(5):645–654.
3. PDQ Adult Treatment Editorial Board. Small Cell Lung Cancer Treatment (PDQ®) Health Professional Version. Published online: May 1, 2019. Available at https://www.ncbi.nlm.nih.gov/books/NBK65909/ (accessed 8 October 2019)
4. [ii] Cancer Council https://www.cancer.org.au/about-cancer/types-of-cancer/lung-cancer.html
5. Simos D, et al, Third line chemotherapy in SCLC: an international analysis. Clin Lung Cancer (2014) 15 (2): 110-8

6. Pelayo Alvarez M, et al. Chemotherapy versus best supportive care for extensive sclc. Cochrane Database Syst Rev (2013) 11: CD001990