



PharmaMar announces Singapore Health Sciences Authority approval of Zepzelca® (lurbinectedin) for the treatment of metastatic Small Cell Lung Cancer

- **Lurbinectedin approval represents an important advance for adult patients whose metastatic Small Cell Lung Cancer has progressed on or after platinum-based chemotherapy.**
- **Singapore Health Sciences Authority and US FDA collaborated via 'Project Orbis' initiative to accelerate availability to Singapore patients.**

Madrid, September 22nd, 2021. – PharmaMar (MSE:PHM) has announced today that its licensing partner, Specialised Therapeutics Asia, Pte. Ltd. (STA) has received provisional marketing approval for Zepzelca® (lurbinectedin) by the Singapore Health Sciences Authority (HSA) for the treatment of adult patients with metastatic small cell lung cancer (SCLC) who have progressed after prior platinum-containing chemotherapy¹. This means, patients who have progressed after front line treatment will now have a further therapeutic option.

Lurbinectedin is the first new therapy approved by the HSA to treat second-line SCLC in more than two decades. The Singapore approval follows on from approvals by the US Food and Drug Administration (FDA)², as well as the Therapeutic Goods Administration (TGA) in Australia³.

Lung Cancer Oncologist and past president of Australasian Lung Cancer Trials Group **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, adding that fewer than 5% of these patients currently survived more than five years post diagnosis^{4,5}. *"The new availability of lurbinectedin 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 lurbinectedin has been granted following collaboration with the US FDA via 'Project Orbis' initiative, due to the high unmet clinical need in SCLC. It is based on monotherapy clinical data from the open-label, multi-center, single-arm study in 105 adult patients with SCLC, who had disease progression after treatment with platinum-based chemotherapy.

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

Lurbinectedin is being made available in Singapore by an independent pharmaceutical company, Specialised Therapeutics, under exclusive license from its 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 therapeutic 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."*

PharmaMar president **José María Fernández, Ph.D.**, said the Company was delighted Singaporean patients would now be provided access to lurbinectedin. *"We are pleased to bring a new treatment choice to relapsed SCLC patients. The accelerated approval of lurbinectedin underscores its potential to fill an unmet need in this often-overlooked SCLC community."*

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

Legal warning



This press release does not constitute an offer to sell or the solicitation of an offer to buy securities, and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of that jurisdiction.

About PharmaMar

PharmaMar is a biopharmaceutical company focused on the research and development of new oncology treatments, whose mission is to improve the healthcare outcomes of patients afflicted by serious diseases with our innovative medicines. The Company is inspired by the sea, driven by science, and motivated by patients with serious diseases to improve their lives by delivering novel medicines to them. PharmaMar intends to continue to be the world leader in marine medicinal discovery, development and innovation. PharmaMar has developed and now commercializes Yondelis® in Europe by itself, as well as Zepzelca® (lurbinectedin), in the US; and Aplidin® (plitidepsin), in Australia, with different partners. In addition, it has a pipeline of drug candidates and a robust R&D oncology program. PharmaMar has other clinical-stage programs under development for several types of solid cancers: lurbinectedin and PM14. Headquartered in Madrid (Spain), PharmaMar has subsidiaries in Germany, Italy, France, Switzerland, Belgium, Austria and the United States. PharmaMar also wholly owns other companies: GENOMICA, a molecular diagnostics company; and Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi). To learn more about PharmaMar, please visit us at www.pharmamar.com.

About Specialised Therapeutics

Headquartered in Singapore, Specialised Therapeutics (ST) 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. 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 lurbinectedin

Lurbinectedin (Zepzelca®), also known as PM1183, is an analog of the marine compound ET-736 isolated from the sea squirt *Ecteinacidia turbinata* in which a hydrogen atom has been replaced by a methoxy group. It is a selective inhibitor of the oncogenic transcription programs on which many tumors are particularly dependent. Together with its effect on cancer cells, lurbinectedin inhibits oncogenic transcription in tumor-associated macrophages, downregulating the production of cytokines that are essential for the growth of the tumor. Transcriptional addiction is an acknowledged target in those diseases, many of them lacking other actionable targets.

Media Contact:

Alfonso Ortín – Communications Director aortin@pharmamar.com Mobile: +34 609493127
Miguel Martínez-Cava – Communication Manager mmartinez-cava@pharmamar.com Mobile: +34 606597464

Phone: +34 918466000

Capital Markets & Investor Relations:

José Luis Moreno– Capital Markets & Investor Relations Director
María Marín de la Plaza – Capital Markets & Investor Relations
investorrelations@pharmamar.com
Phone: +34 914444500



Or please visit our website at www.pharmamar.com

¹ Lurbinectedin HSA Approved Singapore Prescribing Information.

² Lurbinectedin FDA Approved US Prescribing Information:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213702s000lbl.pdf

³ Lurbinectedin TGA Approved Australian Prescribing Information:

<https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2021-PI-02108-1&d=20210914172310101>

⁴ 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)

⁵ Cancer Council <https://www.cancer.org.au/about-cancer/types-of-cancer/lung-cancer.html>

⁶ 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; 21(5):645–654.

⁷ Singapore Cancer Society. <https://www.singaporecancersociety.org.sg/learn-about-cancer/types-of-cancer/lung-cancer.html>

⁸ Singapore Cancer Registry Annual Report 2018.

https://www.nrdo.gov.sg/docs/librariesprovider3/default-document-library/scr-annual-report-2018.pdf?sfvrsn=bcf56c25_0