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In accordance with article 227 of the recast Spanish Securities Market Act (*texto refundido de la Ley del Mercado de Valores*), approved by Royal Legislative Decree 4/2015, of 23 October, and related provisions, is hereby reported the following:

OTHER RELEVANT INFORMATION

Pharma Mar, S.A. announces that its licensing partner, Specialised Therapeutics Asia, Pte. Ltd. (STA) has received provisional marketing approval for Zepzelca® (lurbinectedin) by the Australian Therapeutic Goods Administration (TGA), for the treatment of patients with metastatic Small Cell Lung Cancer (SCLC), that have progressed on or after prior platinum-containing therapy. This means patients who have progressed after other existing treatment options will now be able to access another line of therapy.

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

Please find attached press release that Pharma Mar, S.A. will distribute to the media.

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PharmaMar announces that Australia approves Zepzelca® (lurbinectedin) for the treatment of metastatic Small Cell Lung Cancer

- **The US FDA and the Australian TGA have collaborated via 'Project Orbis' to accelerate availability of lurbinectedin for Australian patients.**
- **Important advance for adult patients whose metastatic SCLC has progressed on or after platinum-based chemotherapy.**

Madrid, September 14th, 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 Australian Therapeutic Goods Administration (TGA), for the treatment of patients with metastatic Small Cell Lung Cancer (SCLC), that have progressed on or after prior platinum-containing therapy[1]. This means patients who have progressed after other existing treatment options will now be able to access another line of therapy.

Lurbinectedin 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 at the Austin Hospital in Melbourne, Australia, 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[2,3]. "*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 TGA approval of lurbinectedin has been granted under a provisional regulatory pathway. The US Food and Drug Administration (FDA) and Australia's TGA collaborated via 'Project Orbis' to accelerate availability to Australian patients.

Lurbinectedin's approval is based on clinical data from an open-label, multi-center, single-arm phase II study in 105 adult patients with SCLC who had disease progression after treatment with platinum-based chemotherapy[4].

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 of 5.3 months as measured by investigator assessment (30% and 5.1 months respectively, as measured by an independent review committee (IRC)[4].

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.

Lurbinectedin is being made available in Australia by the independent pharmaceutical Company, STA, under an exclusive license from international partner, PharmaMar.

José María Fernández, Ph.D., President of PharmaMar said the Company was delighted Australian 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.*" And added: "*We are very thankful that the TGA has been the first regulatory agency to authorize three compounds from PharmaMar.*"

STA Chief Executive Officer, **Carlo Montagner** said the approval of lurbinectedin 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 area where there is an unmet need and SCLC is certainly one of these areas. We look forward to making a difference for these patients and their families.*"

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

Commercial supplies of lurbinectedin in Australia will commence early 2022.

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. 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 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.

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[1] Lurbinectedin Australian Prescribing Information
[2] 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)
[3] Cancer Council https://www.cancer.org.au/about-cancer/types-of-cancer/lung-cancer.html
[4] 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.