

CNMV Markets Directorate General C/ Edison núm. 4 28006 Madrid

Madrid, December 12, 2023

In accordance with the provisions of article 227 of the Spanish Securities Markets and Investment Services Act (*Ley de los Mercados de Valores y de los Servicios de Inversión*), approved by Law 6/2023, of 17 March, and concordant provisions, is hereby reported the following:

# OTHER RELEVANT INFORMATION

Pharma Mar, S.A. announces that its licensing partner, Luye Pharma Group Ltd, has received marketing approval for Zepzelca® (lurbinectedin) by the Pharmacy and Poisons Board of the Hong Kong Special Administrative Region (SAR) for the treatment of adult patients with metastatic Small Cell Lung Cancer (SCLC) with disease progression upon or after receiving platinum-based chemotherapy.

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



# PharmaMar announces the approval of Zepzelca® (lurbinectedin) for the treatment of relapsed Small Cell Lung Cancer in Hong Kong

 This treatment is now available to patients in 16 territories around the world, mainly in Asia and the Americas.

Madrid, December 12<sup>th</sup>, 2023.- PharmaMar (MSE:PHM) has announced today that its licensing partner, Luye Pharma Group Ltd, has received marketing approval for Zepzelca<sup>®</sup> (lurbinectedin) by the Pharmacy and Poisons Board of the Hong Kong Special Administrative Region (SAR), for the treatment of adult patients with metastatic Small Cell Lung Cancer (SCLC) with disease progression upon or after receiving platinum-based chemotherapy.

The approval of lurbinectedin in Hong Kong is based on the data of the open-label, multi-center, single-arm monotherapy clinical trial in 105 adult patients with relapsed SCLC (including patients with platinum-sensitive and platinum-resistant disease), which is the same that the Food and Drug Administration (FDA) used to grant accelerated approval for lurbinectedin.

Lung cancer is the most common of all cancers in Hong Kong, in terms of incidence and mortality. In 2020, 5,422 new cases were diagnosed<sup>1</sup>, of which SCLC accounts for 13-17%<sup>2</sup>, and a total of 3,910 people died from this pathology in that region, representing 26.4% of all cancer deaths<sup>1</sup>.

Currently, lurbinectedin is under review for its New Drug Application (NDA) in mainland China and other countries around the world. Lurbinectedin is now approved in 16 territories: 9 in Asia (United Arab Emirates, Singapore, South Korea, Qatar, Israel, Oman, Taiwan, Macau and Hong Kong); 5 in the Americas (U.S.A, Canada, Ecuador, Mexico and Peru); 1 in Oceania (Australia) and 1 in Europe (Switzerland). Patients in the other European Countries currently can only benefit from Iurbinectedin

<sup>&</sup>lt;sup>1</sup>Cancer Online Resource Hub - Cancers in Hong Kong - Common cancers in Hong Kong - Lung cancer. (s. f.). https://www.cancer.gov.hk/en/hong\_kong\_cancer/common\_cancers\_in\_hong\_kong/lung\_cancer.html

<sup>&</sup>lt;sup>2</sup> The Working Committee of Chinese Society of Clinical Oncology Guidelines. The 2023 Chinese Society of Clinical Oncology Guidelines for Small Cell Lung Cancer. People's Medical Publishing House. 2023.



through compassionate use or in a clinical trial. In order to submit in Europe the dossier for approval, the LAGOON Phase III trial is being conducted.

#### 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, ecubectedin, PM534 and PM54. It also has a preclinical and clinical program in virology. Headquartered in Madrid (Spain), PharmaMar has subsidiaries in Germany, France, Italy, Belgium, Austria, Switzerland and The United States. PharmaMar also wholly owns Sylentis, a company dedicated to researching therapeutic applications of gene silencing (RNAi). To learn more about PharmaMar, please visit us at <a href="https://www.pharmamar.com">www.pharmamar.com</a>

## About Zepzelca®

Zepzelca<sup>®</sup> (lurbinectedin), also known as PM1183, is an analog of the marine compound ET-736 isolated from the sea squirt *Ecteinascidia 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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