

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

Madrid, July 11, 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, Lotus Pharmaceutical CO., Ltd., has received accelerated marketing approval for Zepzelca® (lurbinectedina) by the Taiwan Food and Drug Administration (TFDA), for the treatment of adult patients with metastatic Small Cell Lung Cancer (SCLC) with disease progression on or after 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 metastatic Small Cell Lung Cancer in Taiwan

- Lurbinectedin is now approved in 12 countries around the world.
- It is the first new treatment in more than a decade for metastatic Small Cell Lung Cancer in second line.

Madrid, July 11th, 2023.- PharmaMar (MSE:PHM) has announced today that its licensing partner, Lotus Pharmaceutical CO., Ltd. (TWSE:1795), has received accelerated marketing approval for Zepzelca® (lurbinectedin) by the Taiwan Food and Drug Administration (TFDA), for the treatment of adult patients with metastatic Small Cell Lung Cancer (SCLC) with disease progression on or after platinum-based chemotherapy. It had been more than 10 years since a drug had been approved in Taiwan for this therapeutic indication.

This new approval of lurbinectedin is based on the data from the open-label, multicenter, single-arm monotherapy clinical trial in 105 adult patients with relapsed SCLC (including patients with platinum-sensitive and platinum-resistant disease), that the Food and Drug Administration (FDA) used to grant accelerated approval for lurbinectedin in the US.

In November 2021, PharmaMar and Lotus Pharmaceutical signed a licensing agreement for lurbinectedin in Taiwan. Under the terms of the agreement PharmaMar will retain production rights and will sell the product to Lotus for its clinical and commercial use, while Lotus will pursue the marketing approval in Taiwan and have the right to market the compound exclusively.

The approval is subject to confirmation with a Phase III clinical trial. With this approval in Taiwan, lurbinectedin is now approved in 12 countries around the world.

About 15% of all lung cancers are Small Cell Lung Cancer (SCLC). This type of lung cancer tends to grow and spread faster than Non Small Cell Lung Cancer. In most



people with SCLC, the cancer has already spread beyond the lungs at the time it is diagnosed <sup>1</sup>.

# 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® (lurbinectedin), 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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<sup>&</sup>lt;sup>1</sup> What Is Lung Cancer? (s. f.-a). <a href="https://www.cancer.org/cancer/types/lung-cancer/about/what-is.html">https://www.cancer.org/cancer/types/lung-cancer/about/what-is.html</a>













Or please visit our website at www.pharmamar.com