

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

Madrid, January 31, 2023

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, Megapharm Ltd., has received the conditional marketing approval for Zepzelca® (lurbinectedin) by the Ministry of Health of Israel 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.

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# PharmaMar announces the approval of Zepzelca<sup>®</sup> (lurbinectedin) for the treatment of metastatic Small Cell Lung Cancer in Israel

• Lurbinectedin will become commercially available in Israel in the coming months.

Madrid, January 31<sup>st</sup>, 2023. – PharmaMar (MSE:PHM) has announced today that its licensing partner, Megapharm Ltd., has received the conditional marketing approval for Zepzelca<sup>®</sup> (lurbinectedin) by the Ministry of Health of Israel for the treatment of adult patients with metastatic Small Cell Lung Cancer (SCLC) with disease progression on or after platinum-based chemotherapy.

This new approval of lurbinectedin is based on the monotherapy clinical data from the open-label, multi-center, single-arm 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.

**Ali Zeaiter**, **M.D.**, VP Clinical Development & Regulatory Affairs of PharmaMar, said: "Lurbinectedin is an innovative medicine that shows clinical benefit for patients with relapsed Small Cell Lung Cancer (SCLC). This approval brings hope that, after two decades of no advances in second-line SCLC treatments, many patients with relapsed SCLC in Israel will have a new treatment option available."

In May 2020, PharmaMar and Megapharm signed a licensing agreement for lurbinectedin in Israel. This approval allows Megapharm to market lurbinectedin in Israel in the following months.

The conditional approval is subject to confirmation with the LAGOON Phase III clinical trial in 2<sup>nd</sup> line SCLC, initiated in December 2021.

### 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 developed Yondelis®, which is approved for marketing in more than 70 countries and which PharmaMar markets in Europe. PharmaMar has also developed other products such as Zepzelca® (lurbinectedin), which has obtained conditional approval for marketing in second-line treatment of smallcell lung cancer (SCLC) in the United States; and Aplidin® (plitidepsin), which has been approved for marketing in Australia. These two products, as well as Yondelis<sup>®</sup>, are marketed outside Europe through various partners. PharmaMar also has a pipeline of drug candidates and a solid oncology R&D program. PharmaMar has other clinical-stage programs under development for several types of solid cancers: lurbinectedin and ecubectedin. 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 www.pharmamar.com.

#### About lurbinectedin

Zepzelca<sup>®</sup> (lurbinectedin), also known as PM1183, is an analogue 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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Or please visit our website at www.pharmamar.com