

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

Madrid, August 5, 2022

In accordance with article 227 of the recast Spanish Securities Market Act (*texto refundido de la Ley del Mercado de Valores*), is hereby reported the following:

# OTHER RELEVANT INFORMATION

Pharma Mar, S.A. announces that lurbinectedin has received today the Innovation Passport (Innovative Medicine Designation) by the MHRA (UK Medicines and Healthcare products Regulatory Agency).

Please find attached press release that will be distributed to the media today.



# Lurbinectedin receives the Innovative Medicine Designation by the UK's MHRA

Madrid, August 5<sup>th</sup>, 2022. – PharmaMar (MSE:PHM) has announced today that Zepzelca<sup>®</sup> (Iurbinectedin) has received the Innovation Passport (Innovative Medicine Designation) by the MHRA (UK Medicines and Healthcare products Regulatory Agency).

The MHRA's Innovative Licensing and Access Pathway (ILAP) aims to accelerate the time to market, facilitating patient access to medicines. The ILAP comprises as the first step an "Innovation Passport" designation which supports innovative approaches to the safe, timely and efficient development of medicines to improve patient access. The criteria for the innovation passport include where the condition is life-threatening or seriously debilitating, or where there is a significant patient or public health need and where the medicinal product has the potential to offer benefits to patients (improved efficacy or safety, improved patient care or quality of life as compared to alternative therapeutic options).

Ali Zeaiter, M.D., VP Clinical Development & Regulatory Affairs of PharmaMar, said: "Lurbinectedin is an innovative medicine that showed clinical benefit for patients with relapsed Small Cell Lung Cancer (SCLC) and obtained provisional approvals in a number of countries (including USA, Canada and Australia) and is being developed in other clinically significant indications. SCLC represents an unmet medical need in the UK and worldwide, and our objectives are aligned with those of the UK public health authorities to facilitate and improve patients access to medicines such as lurbinectedin," and added: "We believe that the innovation passport designation is an important step towards facilitating SCLC patients' access to a new treatment option."

On May 4<sup>th</sup> 2022, PharmaMar announced it had submitted a conditional marketing authorization application to the UK's MHRA for the treatment with lurbinectedin in adult patients with metastatic Small Cell Lung Cancer who have progressed following prior platinum-based chemotherapy based on data from the Phase II basket trial with lurbinectedin in monotherapy. PharmaMar expects a response to such application by



the end of this year or first quarter of 2023. In addition, the LAGOON Phase III trial could be used as a confirmatory trial.

On 2020 PharmaMar and Immedica Pharma AB signed an agreement for the exclusive distribution and marketing of lurbinectedin for the UK and other territories.

## 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 ecubectedin. Headquartered in Madrid (Spain), PharmaMar has subsidiaries in Germany, France, Italy, Belgium, Austria, Switzerland 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 <a href="https://www.pharmamar.com">www.pharmamar.com</a>.

# 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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