



CNMV  
Markets Directorate General  
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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 the initiation of a Phase IIb/III clinical trial (SaLuDo, *Sarcoma patients treated with Lurbinectedin and Doxorubicin*) with lurbinectedin in combination with doxorubicin for the first-line treatment of patients with metastatic Leiomyosarcoma (LMS). The trial will evaluate Progression-Free Survival (PFS) as the primary endpoint and Overall Survival (OS) as one of the secondary endpoints of treatment with the combination of lurbinectedin and doxorubicin compared to the current standard of care in Leiomyosarcoma, which is doxorubicin.

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



## PharmaMar initiates a Phase IIb/III clinical trial of Zepzelca® (lurbinectedin) for the treatment of patients with metastatic Leiomyosarcoma

- SaLuDo is a global, open-label, multicenter and randomized clinical trial conducted in more than 76 centres in the United States and Europe.
- The primary objective of the SaLuDo trial is to evaluate the Progression-Free Survival of the combination of lurbinectedin and doxorubicin versus single-agent doxorubicin in the first-line treatment of metastatic leiomyosarcoma.

Madrid, October 31<sup>st</sup>, 2023. – PharmaMar (MSE:PHM) has announced today the initiation of a Phase IIb/III clinical trial (SaLuDo, ***Sarcoma patients treated with Lurbinectedin and Doxorubicin***)) with lurbinectedin in combination with doxorubicin for the first-line treatment of patients with metastatic Leiomyosarcoma (LMS). The trial will evaluate Progression-Free Survival (PFS) as the primary endpoint and Overall Survival (OS) as one of the secondary endpoints of treatment with the combination of lurbinectedin and doxorubicin compared to the current standard of care in Leiomyosarcoma, which is doxorubicin.

This clinical trial consists of 2 phases. Phase IIb includes three treatment arms: two arms will evaluate the combination of lurbinectedin plus doxorubicin at different doses, and the control arm will evaluate single-agent doxorubicin. At the end of this phase, the best combination scheme of the lurbinectedin plus doxorubicin combination will be chosen to continue with phase III in which the chosen combination scheme will be compared with doxorubicin administered as a single agent.

The trial will be conducted in patients with metastatic LMS as a first line of treatment. Leiomyosarcoma is a subtype of Soft Tissue Sarcoma (STS) that accounts for 10-20% of all cases. Due to the low frequency of STS (1% of all cancers seen in adult



population), Leiomyosarcoma is categorized as a "rare tumor". Leiomyosarcoma originates in smooth muscles. The body contains smooth muscle tissue in hollow organs (intestines, stomach or bladder), as well as in blood vessels (including the extremities) and in women, there are also smooth muscles in the uterus.<sup>1</sup>

The SaLuDo trial involves 76 centers in the United States and several European countries, including Spain.

*"We are initiating this trial for the treatment of a pathology that today has few therapeutic alternatives for patients despite representing one of the most common sarcoma subtypes. With the promising results presented recently at ASCO this year from a phase Ib presented by Dr Gregory Cote<sup>2</sup>, lurbinectedin in combination with doxorubicin would be a better option for patients with this pathology in first line treatment if the trial confirms the endpoint,"* commented Dr. Ali Zeaiter, VP and Head of Clinical Development at PharmaMar.

#### **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 [www.pharmamar.com](http://www.pharmamar.com).

#### **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

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<sup>1</sup>Cancer statistics, 2023. Siegel RL, Miller KD, Wagle NS, Jemal A. CA Cancer J Clin. 2023;73(1): 17.

<sup>2</sup> Efficacy of combination lurbinectedin (LURBI) + doxorubicin (DOX) from the phase 1B soft-tissue sarcoma (STS) lead-in to a randomized phase 2 trial in leiomyosarcoma (LMS)"



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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