

PharmaMar announces the approval of Zepzelca® (lurbinectedin) for the treatment of metastatic Small Cell Lung Cancer in Switzerland

- **First approval in Europe for lurbinectedin.**

Madrid, March 8th, 2023. – PharmaMar (MSE:PHM) has announced today that it has received the Temporary Authorisation for the commercialization of Zepzelca® (lurbinectedin) by the Swiss Agency for Therapeutic Products (Swissmedic) for the treatment of adult patients with metastatic Small Cell Lung Cancer (SCLC) with disease progression on or after platinum-based chemotherapy without central nervous system (CNS) metastases.

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, platinum-resistant and platinum refractory disease), that the Food and Drug Administration (FDA) used to grant accelerated approval for lurbinectedin in the US.

Temporary authorisation is granted under certain conditions defined by law in order to make medicinal products for the treatment of life-threatening diseases with limited therapeutic options available to patients as quickly as possible.

Luis Mora, Managing Director of the PharmaMar's Oncology & Virology Business Units, said: *"We are very pleased to announce for patients that Switzerland is the first country in Europe to approve lurbinectedin. It will be marketed directly by PharmaMar's team. This approval brings hope for many patients with metastatic SCLC in Switzerland, who will now have a new treatment option."*

The temporary authorisation is subject to confirmation with the LAGOON Phase III clinical trial in 2nd 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 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 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® (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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