



PharmaMar announces the approval of Zepzelca™ (lurbinectedin) for the treatment of relapsed stage III or metastatic small cell lung cancer in Canada

- **Lurbinectedin to become commercially available in Canada in the coming months.**

Madrid, September 30th, 2021. – PharmaMar (MSE:PHM) has announced today that its licensing partner, Jazz Pharmaceuticals plc (Nasdaq: JAZZ), has received conditional approval from Health Canada for Zepzelca™ (lurbinectedin) for the treatment of adult patients with relapsed stage III or metastatic small cell lung cancer (SCLC), with disease progression on or after platinum-based chemotherapy. Lurbinectedin will be available in Canada later this year.

This new approval of lurbinectedin is based on the same monotherapy clinical data from the open-label, multi-center, single-arm study in 105 adult patients with relapsed SCLC¹ (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. The data, which was published in the May 2020 issue of *The Lancet Oncology*, showed that in relapsed SCLC, lurbinectedin demonstrated an Objective Response Rate (ORR) of 35% and a median Duration of Response (DoR) of 5.3 months as measured by investigator assessment (30% and 5.1 months respectively, as measured by an independent review committee (IRC)).

The conditional approval is subject to confirmation in a Phase III study in 2nd line SCLC, planned to be initiated by the end of 2021.

"We are pleased to bring a new treatment choice to Canadian patients with relapsed SCLC," said **José María Fernández**, PhD, President of PharmaMar. *"Canada is the fifth country to approve lurbinectedin for the treatment of SCLC, following in the footsteps of the United States, the United Arab Emirates and, more recently, Australia and Singapore. We are confident that further approvals will be granted soon in more countries."*



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 PM14. Headquartered in Madrid (Spain), PharmaMar has subsidiaries in Germany, Italy, France, Belgium, Austria 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 www.pharmamar.com.

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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¹ Trigo J, Subbiah V, Besse B, et al. Lurbinectedin as second-line treatment for patients with small-cell lung cancer: a single-arm, open-label, phase 2 basket trial. *Lancet Oncol.* 2020 May;21(5):645-654.