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In accordance with the provisions of article 226 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:

### **INSIDE INFORMATION**

Pharma Mar, S.A. and its partner Jazz Pharmaceuticals plc announce positive top-line results from the Phase 3 clinical trial evaluating Zepzelca® (lurbinectedin) in combination with the PD-L1 inhibitor atezolizumab (Tecentriq®) compared to atezolizumab alone when administered as a maintenance treatment for adults with extensive-stage Small Cell Lung Cancer (ES-SCLC) following induction therapy with carboplatin, etoposide and atezolizumab.

The combination of lurbinectedin and atezolizumab demonstrated a statistically significant improvement and clinically meaningful in the primary endpoints of overall survival (OS) and progression-free survival (PFS), as assessed by an independent review facility (IRF), compared to treatment with atezolizumab alone.

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

**Pharma Mar S.A.**  
**Avda. de los Reyes, 1**  
**P.I. La Mina**  
**28770 Colmenar Viejo**  
**(Madrid) Spain**  
**[www.pharmamar.com](http://www.pharmamar.com)**

**PharmaMar Announces Positive and Statistically Significant Overall Survival and Progression-Free Survival Results for Zepzelca® (lurbinectedin) and Atezolizumab Combination in First-Line Maintenance Therapy for Extensive-Stage Small Cell Lung Cancer**



- Jazz plans to submit supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) and PharmaMar will submit Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) in first half of the year 2025 for this combination therapy as a first-line maintenance treatment for ES-SCLC.

**Madrid, October 15<sup>th</sup>, 2024.-** PharmaMar (MSE: PHM) and its partner Jazz Pharmaceuticals plc (Nasdaq: JAZZ) have announced today positive top-line results from the Phase 3 clinical trial evaluating Zepzelca® (lurbinectedin) in combination with the PD-L1 inhibitor atezolizumab (Tecentriq®) compared to atezolizumab alone when administered as a maintenance treatment for adults with extensive-stage Small Cell Lung Cancer (ES-SCLC) following induction therapy with carboplatin, etoposide and atezolizumab. The combination of lurbinectedin and atezolizumab demonstrated a statistically significant improvement in the primary endpoints of overall survival (OS) and progression-free survival (PFS), as assessed by an independent review facility (IRF), compared to treatment with atezolizumab alone.

*“Each year, approximately 63,000 to 72,000 new cases of Small Cell Lung Cancer (SCLC) are reported in Europe. A majority of these patients are diagnosed with extensive stage disease, which is aggressive and often difficult to treat, with poor prognosis,<sup>i,ii,iii</sup>”* said Luis Paz-Ares, M.D., Ph.D., head of medical oncology at the Hospital Universitario 12 de Octubre in Madrid, Spain, and IMforte trial principal investigator. *“These trial results demonstrate the efficacy of lurbinectedin, in combination with standard-of-care atezolizumab for patients in first-line maintenance treatment, a much-needed advancement for patients with extensive disease.”*

*“The results of the Phase 3 IMforte trial are highly encouraging and showed a statistically significant benefit for the lurbinectedin and atezolizumab combination for extensive-stage small cell lung cancer patients receiving this treatment in the first-line maintenance setting. These results demonstrate the potential of this regimen to delay disease progression and extend survival for patients with this aggressive disease,”* said Rob Iannone, M.D., M.S.C.E., executive vice president, global head of research and development, and chief medical officer of Jazz Pharmaceuticals. *“We are pleased with these clinically meaningful results and plan to submit an sNDA in the first half of 2025 to support this combination in the first-line maintenance setting. We thank the investigators and patients who are involved in this trial, along with our partners at Roche.”*

*“Lurbinectedin monotherapy is currently the standard of care in 2L SCLC. In Europe, it is only approved in Switzerland and early access and compassionate use programs have already allowed some European patients to benefit from lurbinectedin,”* said Javier Jiménez, Chief Medical Officer of PharmaMar.

The combination was generally well-tolerated. The preliminary safety data in the ongoing trial is consistent with the known safety profiles of lurbinectedin and atezolizumab with no new safety signals observed in the combination arm.

Jazz and Roche plan to submit these data for presentation at a future medical meeting.

PharmaMar will submit a marketing authorisation application (MAA) to the EMA in the first half of 2025 to request regulatory approval in the European Union (EU).

Lurbinectedin is available for use in 16 territories around the world.

#### **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. 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 the IMforte Phase 3 Trial**

IMforte ([NCT05091567](https://clinicaltrials.gov/ct2/show/study/NCT05091567)) is an ongoing Phase 3, randomized, multicenter maintenance trial evaluating the efficacy, safety and pharmacokinetics of *lurbinectedin* plus *atezolizumab* in adults (≥18 years) with ES-SCLC following induction therapy with carboplatin, etoposide and atezolizumab. The primary endpoints for this study are OS and IRF-assessed PFS.

The trial consists of two phases: an induction phase and a maintenance phase. Participants were required to have an ongoing response or stable disease per the Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 after the induction phase of four cycles of carboplatin, etoposide, and atezolizumab to be considered for eligibility screening for the maintenance phase. Eligible participants were randomized in a 1:1 ratio to receive either lurbinectedin plus atezolizumab or atezolizumab in the maintenance phase.

The trial is sponsored by Roche and co-funded by Jazz Pharmaceuticals. Additional information about the trial, including eligibility criteria and a list of clinical trial sites, can be found at: <https://clinicaltrials.gov> (ClinicalTrials.gov Identifier: NCT05091567).

#### **About Zepzelca®**

Zepzelca® (lurbinectedin), also known as PM1183, is an analog of the marine compound ET-736 isolated from the sea squirt Ecteinascidia 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.

#### **Media Contact:**

Lara Vadillo – Communication Director [lvadillo@pharmamar.com](mailto:lvadillo@pharmamar.com)

Miriam Collados Gordo – Corporate Communication Manager [mcollados@pharmamar.com](mailto:mcollados@pharmamar.com)

Phone: +34 918466000

#### **Capital Markets & Investor Relations:**

José Luis Moreno – VP Capital Markets & Investor Relations

Natalia Amo – Capital Markets & Investor Relations

[investorrelations@pharmamar.com](mailto:investorrelations@pharmamar.com)

Phone: +34 914444500



Or please visit our website at [www.pharmamar.com](http://www.pharmamar.com)

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<sup>i</sup> Cancer today. (s. f.). <https://gco.iarc.who.int/today/en/fact-sheets-populations#regions>

<sup>ii</sup> Alvarado-Lunda G, Morales-Espinosa D. Treatment for small cell lung cancer, where are we now? – A review. *Transl Lung Cancer Res.* 2016;5(1):26-38.

<sup>iii</sup> SEER Explorer Lung and Bronchus Cancer, Recent Trends in SEER Incidence Rates, 2000-2016, by Age, <https://seer.cancer.gov/explorer> Updated June 27, 2024. Accessed October 10, 2024.