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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 that positive results from the Phase 3 IMforte study of Zepzelca® (lurbinectedin) in combination with atezolizumab (Tecentriq®) as a first-line maintenance treatment for people with extensive-stage small cell lung cancer (ES-SCLC), following induction therapy with carboplatin, etoposide and atezolizumab have been presented in an oral session at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago and published simultaneously in The Lancet.

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

# PharmaMar presents at ASCO that the Zepzelca® (lurbinectedin) and atezolizumab (Tecentriq®) combination significantly improves survival as first-line maintenance therapy for extensive-stage small cell lung cancer



- **First-line maintenance combination therapy reduced the risk of disease progression or death by 46%, with a median overall survival of 13.2 months vs 10.6 months for atezolizumab alone from the point of randomization**
- **First Phase 3 study to demonstrate statistically significant and clinically meaningful improvements in both progression-free and overall survival in ES-SCLC first-line maintenance**
- **PharmaMar has submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for lurbinectedin**
- **Results presented at the ASCO 2025 Annual Meeting and simultaneously published in The Lancet**
- **PharmaMar to host a webcast with Key Opinion Leaders on Thursday, June 12<sup>th</sup>, to review lurbinectedin data**

**Madrid, June 3<sup>rd</sup>, 2025.** PharmaMar (MSE:PHM) has announced positive results from the Phase 3 IMforte study of Zepzelca® (lurbinectedin) in combination with atezolizumab (Tecentriq®) as a first-line maintenance treatment for people with extensive-stage small cell lung cancer (ES-SCLC), following induction therapy with carboplatin, etoposide and atezolizumab. The study met both primary endpoints, demonstrating statistically significant improvements in progression-free survival (PFS) and overall survival (OS) compared to atezolizumab alone.

IMforte is the first global Phase 3 trial to demonstrate clinically meaningful PFS and OS benefits in the first-line maintenance setting for ES-SCLC and supports maintenance therapy with lurbinectedin plus atezolizumab as a new standard of care for patients. The data were presented today in an oral session at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago and published simultaneously in The Lancet. Data from the trial served as the basis for the supplemental New Drug Application (sNDA) submission to the FDA by Jazz Pharmaceuticals, as well as for the submission of a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) by PharmaMar.

Following induction therapy with carboplatin, etoposide and atezolizumab, patients who did not have disease progression were randomized to receive lurbinectedin plus atezolizumab or atezolizumab alone. From the point of randomization, the median PFS was 5.4 months for the lurbinectedin plus atezolizumab combination versus 2.1 months

for atezolizumab alone (stratified HR = 0.54, 95% CI: 0.43–0.67;  $p < 0.0001$ ), and median OS was 13.2 months versus 10.6 months (stratified hazard ratio [HR] = 0.73; 95% CI: 0.57–0.95;  $p = 0.0174$ ). The combination reduced the risk of disease progression or death by 46% and the risk of death by 27% compared to atezolizumab alone. The lurbinectedin plus atezolizumab combination had no new or unexpected safety signals.

*“Small cell lung cancer is an aggressive and devastating disease; at the time of diagnosis, the large majority of patients have already progressed to extensive-stage disease and only one out of five survive longer than two years,”* said Luis Paz-Ares, M.D., Ph.D., head of medical oncology at the Hospital Universitario 12 de Octubre in Madrid, Spain, and the IMforte trial principal investigator. *“The IMforte results are very encouraging showing a potentially practice-changing option that could improve survival for patients with a very high unmet need.”*

*“Upon approval, patients will have access to lurbinectedin earlier in the treatment paradigm, where there's potential to increase duration of response in a broader patient population, delaying disease progression and extending survival,”* said Javier Jiménez Jiménez, Chief Medical Officer of PharmaMar.

Each year, approximately 63,000 to 72,000 new cases of small cell lung cancer (SCLC) are reported in Europe. Most 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>

#### **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.

#### **Phase 3 IMforte Trial Results**

These primary results are from the global Phase 3 IMforte trial, which evaluated lurbinectedin plus atezolizumab as a first-line maintenance therapy in patients with ES-SCLC. 483 patients were randomized after completion of 4 cycles of induction therapy with atezolizumab plus carboplatin and etoposide. From the point of randomization, the median OS for the lurbinectedin plus atezolizumab regimen was 13.2 months versus 10.6 months for atezolizumab alone (stratified hazard ratio [HR] = 0.73; 95% CI: 0.57–0.95;  $p = 0.0174$ ). From the point of randomization, the median PFS by independent assessment was 5.4 months versus 2.1 months, respectively (stratified HR = 0.54, 95% CI: 0.43–0.67;  $p < 0.0001$ ). Treatment duration for patients in the lurbinectedin plus atezolizumab arm was twice as long as the atezolizumab arm, with a median maintenance treatment duration of 4.2 months versus 2.1 months, respectively.

The lurbinectedin plus atezolizumab combination as maintenance therapy was generally well tolerated with no new safety signals identified. In the lurbinectedin plus atezolizumab and atezolizumab arms, respectively, treatment-related adverse events (TRAEs) occurred in 83.5% versus 40.0% of patients, with Grade 3-4 TRAEs in 25.6% versus 5.8% and Grade 5 TRAEs in 0.8% (two patients with sepsis and febrile neutropenia) versus 0.4% (one patient with sepsis). AEs led to treatment discontinuation in 6.2% of patients in the lurbinectedin plus atezolizumab arm and 3.3% of patients in the atezolizumab arm.

PharmaMar will host a Key Opinion Leader webcast on June 12nd to review lurbinectedin data. The webcast will include a discussion panel of Dr. Martin Wermke from TU Dresden and Dr. Nicolas Girard from Institut Curie. The webcast may be accessed from the Investors section at <https://pharmamar.com/en/>

#### **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 pharmacokinetic of lurbinectedin plus atezolizumab, compared with standard-of-care first-line maintenance with atezolizumab alone, 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 in the maintenance phase.

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 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 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.

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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.