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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. announces that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending the approval of Zepzelca® (lurbinectedin) in combination with atezolizumab (Tecentriq®) as first-line maintenance therapy for adult patients with extensive-stage small cell lung cancer (ES-SCLC), whose disease has not progressed after standard induction therapy.

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

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Press release

PharmaMar receives recommendation for the approval from the European Medicines Agency for Zepzelca® (lurbinectedin) for the treatment of extensive-stage small cell lung cancer in combination with the immunotherapy atezolizumab



- The recommendation is based on the results of the IMforte Phase 3 trial, which showed a 46% reduction in the risk of disease progression or death and a 27% reduction in the risk of death compared to atezolizumab monotherapy.
- Lurbinectedin has also received positive opinion for designation as orphan drug in small cell lung cancer.
- In Europe, around 62,000 new cases of small cell lung cancer, the most aggressive type of lung cancer characterized by rapid growth and early spread, are diagnosed each year.

Madrid, March 27th, 2026.- PharmaMar (MSE: PHM), has announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending the approval of Zepzelca® (lurbinectedin) in combination with atezolizumab (Tecentriq®) as first-line maintenance therapy for adult patients with extensive-stage small cell lung cancer (ES-SCLC), whose disease has not progressed after standard induction therapy.

The CHMP's positive opinion is based on data from the Phase 3 IMforte trial, sponsored by Roche in collaboration with Jazz Pharmaceuticals in which the combination of lurbinectedin and atezolizumab was associated with a 46% reduction in the risk of disease progression or death, and a 27% reduction in the risk of death compared with atezolizumab monotherapy.

Dr. Luis Paz-Ares, Head of the Medical Oncology Service at the 12 de Octubre University Hospital in Madrid and principal investigator of the IMforte trial, highlights that: *“This positive opinion represents a significant step forward in providing patients in Europe with access to an innovative therapy for a disease with a particularly poor prognosis. For the first time in this maintenance context, an improvement in overall survival and progression-free survival has been demonstrated, marking a milestone in the treatment of this disease. For healthcare professionals, this advancement provides a new treatment option to offer our patients.”*

Luis Mora, Managing Director of PharmaMar, commented: *“The CHMP's positive opinion represents a very important milestone in facilitating access for European patients to a new therapeutic option. It also represents important recognition of our Company's commitment to research and development of innovative new compounds.”*

The European Commission will now decide on the marketing authorization in accordance with the established procedure. This combination is currently authorized for first-line maintenance treatment in 10 countries including the US, Switzerland, the United Arab Emirates, Oman, Uruguay, Peru, Paraguay, Ecuador, Israel and Taiwan.

Following a positive opinion from the Committee for Orphan Medicinal Products (COMP) of the EMA, lurbinectedin has been approved as an Orphan Medicinal Product for small cell lung cancer. Orphan drug designation is a status granted by the EMA to drugs intended to treat rare or uncommon diseases that affect fewer than 5 people per 10,000 inhabitants in the European Union.

Small cell lung cancer accounts for about 15% of lung cancer cases and is characterized by its aggressive behavior, and an early tendency to spread^{i,ii}. Each year, around 62,000 new cases of SCLCⁱⁱⁱ are diagnosed in Europe, with most patients presenting advanced disease at the time of diagnosis.

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. In addition, Zepzelca® (lurbinectedin), in the US and other countries; and Aplidin® (plitidepsin), in Australia, each 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: 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) and contract-manufacturing (CDMO) of oligonucleotides. For more information, please visit: 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. 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.

Tecentriq (atezolizumab) is a registered trademark of Genentech, a member of the Roche Group.

About the IMforte Phase 3 Trial

The Phase 3 global IMforte trial 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.

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Or please visit our website at www.pharmamar.com

ⁱ General information on small cell lung cancer. [Small Cell Lung Cancer Treatment \(PDQ®\) - NCI](#)

ⁱⁱ [Lung Cancer Statistics | How Common Is Lung Cancer? | American Cancer Society](#)

ⁱⁱⁱ Cancer today. <https://gco.iarc.who.int/today/en/fact-sheets-populations#regions>