

CNMV Markets Directorate General C/ Edison núm. 4 28006 Madrid

Madrid, June 10, 2025

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 that the U.S Food and Drug Administration (FDA) has granted Priority Review for the supplemental New Drug Application (sNDA) for 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.

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

# **Press Release**



# FDA Grants Priority Review for Zepzelca® (lurbinectedin) and atezolizumab (Tecentriq®) combination in Extensive Stage Small Cell Lung Cancer



Madrid, June 10<sup>th</sup>, 2025.- PharmaMar (MSE:PHM) has announced that the U.S Food and Drug Administration (FDA) has granted Priority Review for the supplemental New Drug Application (sNDA) for Zepzelca<sup>®</sup> (lurbinectedin) in combination with atezolizumab (Tecentriq<sup>®</sup>) 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 FDA's Priority Review designation is assigned to applications for drugs that would offer a significant improvement in the safety or effectiveness of the treatment of a serious condition and means FDA's goal is to take action on the NDA within six months (compared to ten months under standard review). The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of October 7, 2025.

Jazz Pharmaceuticals plc (Nasdaq: JAZZ), PharmaMar's partner in the U.S., submitted the sNDA to the FDA in April based on data from the 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. From the point of randomization, the median PFS by independent assessment was 5.4 months versus 2.1 months, respectively.

Data from the trial served as the basis, also, for the recent submission of a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) by PharmaMar.

PharmaMar informs that Slingshot will host a Key Opinion Leader webcast on June 12<sup>th</sup> at 17:00h CEST / 11:00 EDT to review the Phase 3 IMforte data for lurbinectedin + atezolizumab in extensive-stage small cell lung cancer, which were presented at ASCO, as well as the treatment landscape. 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 <a href="https://pharmamar.com/en/">https://pharmamar.com/en/</a>

#### 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 <a href="https://www.pharmamar.com">www.pharmamar.com</a>.

## 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 – Communications director Ivadillo@pharmamar.com Miriam Collados Gordo – Corporate Communications Manager 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

Phone: +34 914444500



Or please visit our website at www.pharmamar.com