

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

Madrid, November 20, 2024

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

By means of a communication of Other Relevant Information dated 8 July 2024 (registration number 29559) Pharma Mar, S.A. informed of the European Commission's Implementing Decision revoking Decision C(2018) 4831 (final), which refused to grant marketing authorisation for the medicinal product for human use 'Aplidin - plitidepsin' and agreed to refer the opinions of the Committee for Medicinal Products for Human Use (CHMP) to the European Medicines Agency (EMA), requesting the re-evaluation of the application for registration of Aplidin from the time of the procedural irregularity detected.

On 15 November 2024, the General Court of the European Union issued an order stating that:

- (i) It is declared that, as a consequence of the revocation of the Decision by the European Commission, the action has become devoid of purpose and that there is no longer any need to adjudicate on it.
- (ii) Orders the European Commission to bear its own costs and to pay the costs incurred by Pharma Mar, S.A. in the proceedings before the General Court of the European Union and the Court of Justice of the European Union.
- (iii) Orders the Federal Republic of Germany, the Republic of Estonia, the Kingdom of the Netherlands and the European Medicines Agency (EMA) to bear their own costs in relation to the appeal proceedings before the Court of Justice of the European Union in Cases C-6/21 P and C-16/21 P and to the proceedings following the referral back to the General Court in Case T-594/18 RENV.

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

# **Press Release**



# The General Court of the EU orders the European Commission to pay the costs in the Aplidin $^\circ$ case



- The European Commission (EC) is ordered to bear its own costs and to pay those incurred by PharmaMar.
- Following the EC's revocation of its initial decision not to grant the Marketing Authorisation of Aplidin<sup>®</sup> (plitidepsin), the General Court closed the legal proceedings.
- The EMA will re-evaluate the drug for Multiple Myeloma.

**Madrid, November 20<sup>th</sup>, 2024**.- The General Court of the European Union has issued an order declaring that the case is without object and that there is no longer any need to adjudicate on it, after the EC revoking its initial decision not to grant plitidepsin Marketing Authorization.

Last July, the EC acknowledged that during the evaluation of plitidepsin there was a conflict of interest in allowing an expert from the Scientific Advisory Group was developing rival products and was working at a company, XNK Therapeutics, that was developing a rival product, also.

PharmaMar has maintained since October 2018, when the initial lawsuit was filed, the existence of a conflict of interest in a manner that has demonstrated the unfairness that occurred.

In this order, the EU General Court orders the EC to bear its own costs and to pay those of PharmaMar (MSE: PHM) in proceedings before the General Court of the EU and before the Court of Justice of the EU. The other parties involved in the case, who were defending the same position as the European Medicines Agency, EMA, i.e. Germany, Estonia, the Netherlands and the EMA itself, shall bear their own costs.

The EMA, at the request of the EC, will re-evaluate plitidepsin for Multiple Myeloma at its own discretion.

The Company will demand the reassessment process to be conducted with absolute impartiality, equality, transparency and compliance by the EMA.

# 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>.

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