CNMV
Markets Directorate General
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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. (the **"Company"**) informs that it has received an Implementing Decision from the European Commission revoking Decision C(2018) 4831 (final), which refused to grant marketing authorisation for the medicinal product for human use «Aplidin – plitidepsina» under Regulation (EC) Number 726/2004 of the European Parliament and of the Council.

By means of a communication of Other Relevant Information dated 28 October 2020 (registration number 5307), the Company informed of the upheld judgment of the General Court of the European Union annulling Commission Implementing Decision C(2018) 4831 (final) of 17 July 2018 refusing marketing authorisation for «Aplidin – plitidepsina». As a consequence of that judgment, the European Commission called on the European Medicines Agency (EMA) to re-examine the marketing authorisation application process for Aplidin, in order to conduct a scientific assessment that would fully ensure compliance with the principle of impartiality and exclude any legitimate doubts about the possible bias of the scientific experts involved in the assessment. However, this judgment was appealed by two Member States, Germany and Estonia, which lodged appeals with the Court of Justice of the European Union (CJEU), resulting in a stay of the new procedure before the EMA.

On 22 June 2023, the CJEU, after ruling on the appeals referred to above, issued a judgment annulling the General Court's judgment and referred the case back to the General Court to rule again on the first ground for annulment raised by the Company in its initial application, namely the infringement of the principle of objective impartiality by the EMA during the application for marketing authorisation for Aplidin, and to rule, if it considered it necessary, on the other grounds for annulment in its application.

According to the communication received by the Company, following the judgment of the Court of Justice of 14 March 2024 in Case C-291/22 P D&A Pharma v. Commission and EMA, EU:C:2024:2283, *"the Commission has reassessed the criteria applied for the participation of experts in the administrative procedure in the Aplidin case and whether the relevant EMA rules governing conflicts of interest can ensure the objective impartiality of such experts"*.

In the light of the clarification provided by the judgment in the D&A Pharma case, the Commission notes that one of the experts of the consulted scientific advisory group involved in the development of a «rival» product was allowed to participate in the marketing authorisation procedure for the medicinal product «Aplidin – plitidepsina», in accordance with the EMA rules applicable at that time.

In order to avoid any doubt as to the objective impartiality of the assessment of the application, the European Commission has considered it appropriate, *"to revoke Commission Implementing Decision*

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C(2018) 4831 (final) and to subsequently refer the CHMP opinions to the EMA, requesting the re-evaluation of the application from the time of the detected procedural irregularity".

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

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Aplidin® will be re-evaluated by the EMA. The European Commission revokes the decision that initially denied PharmaMar's Marketing Authorization for Multiple Myeloma due to a conflict of interest

- **The European Commission (EC) has acknowledged that an expert from the Scientific Advisory Group, who was developing a rival product was allowed to participate in the Marketing Authorization procedure for Aplidin (plitidepsin).**
- **The EC requests the European Medicines Agency, EMA, to re-evaluate the application for Aplidin in Multiple Myeloma.**
- **This exceptional decision supports what PharmaMar has always maintained, namely that there was a conflict of interest among the EMA experts who evaluated the therapy.**
- **The Company will demand the reassessment process to be conducted with absolute impartiality, equality and transparency by the EMA.**

Madrid, July 8th, 2024.- PharmaMar (MSE:PHM) has received a notification from the European Commission (EC) informing the Company of its decision to revoke the refusal to grant Marketing Authorization for Aplidin® in Multiple Myeloma.

According to the communication received, the EC has re-evaluated the criteria applied for the participation of experts in the administrative procedure for the Marketing Authorization of Aplidin, as well as the relevant EMA rules governing conflicts of interest, so that they can ensure the objective impartiality of these experts.

Therefore, the EC notes that one of the experts of the Scientific Advisory Group (SAG) involved in the development of a rival product, was allowed to participate in the Marketing Authorization procedure for Aplidin, in accordance with the EMA rules applicable at the time.

Consequently, in order to avoid any doubt as to the objective impartiality of the assessment of the application, the Commission has decided it is appropriate to revoke the decision to refuse Marketing Authorization for Aplidin.

It is also reported that the Commission has forwarded to the EMA the opinions of the Committee for Medicinal Products for Human Use (CHMP), to request the re-evaluation of the application from the time of the onset of the detected procedural irregularity.

The European Commission's reversal of the decision, which is totally exceptional, is a de facto acknowledgement that PharmaMar did not have all the necessary guarantees in the evaluation process for Aplidin. Now that the registration dossier has been returned to the EMA, the Company will ensure that the procedure is conducted with absolute impartiality and on a level playing field.

History of the lawsuit, 7 years of litigation

PharmaMar filed a lawsuit in October 2018 before the General Court of the European Union against the EC, seeking the annulment of the Commission's Implementing Decision, by which it denied Marketing Authorization for Aplidin as a treatment for patients with Multiple Myeloma.

The reason for the lawsuit related to the strict conflict-of-interest checks carried out by the experts appointed by the EMA and the correct analysis of the scientific evidence presented by PharmaMar.

In October 2020, the General Court of the European Union upheld PharmaMar's claim in full, at the extreme end of the conflict of interest, annulling the European Commission's decision to refuse Marketing Authorization for Aplidin for the treatment of patients with Multiple Myeloma, and ordered the Commission to pay the costs.

In 2021, Estonia and Germany appealed the decision to the EU Court of Justice, although the EC decided not to do it, which could be understood as implicitly accepting the ruling.

In 2023, the Court of Justice of the European Union annulled the judgment of the General Court and referred the case back to the General Court, to rule again on the first ground for annulment urged by PharmaMar in its initial application, and to rule,

if it considered it necessary, on the other claims for annulment in its action. That is, to rule not only on the conflict of interest and the breach of the Principle of Objective Impartiality by the EMA, but also on the breach of the Principle of Good Administration, the breach of the Principle of Equal Treatment and incorrect analysis of the scientific evidence presented by PharmaMar, the breach of the obligation to state reasons and the breach of the rights of defense.

The Company has always maintained that, during the evaluation process of its drug, Aplidin for the treatment of Multiple Myeloma, there was a conflict of interest of several members based on numerous objective elements, including the cooperation of one of its members with a Swedish company, XNK Therapeutics AB, developing a rival drug, as well as its participation in the development of other competing drugs.

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. It also has a preclinical and clinical program in virology. 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

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