



National Securities Market Commission  
Markets Directorate General  
c/ Edison núm. 4  
28006 Madrid

Colmenar Viejo (Madrid), November 15, 2017

Pursuant to article 228 of the consolidated text of the Spanish Securities Market Act, we hereby inform you of the following **SIGNIFICANT EVENT**:

“Pharma Mar, S.A. announces that the Independent Data Monitoring Committee (IDMC) has recommended that the Phase III (ATLANTIS) trial currently under way with Zeposyn® (PM1183) in combination with doxorubicin in small-cell lung cancer patients should continue without any changes. The IDMC's recommendation came after an analysis of the safety data obtained with the first 150 patients treated in the trial. The trial is expected to enroll approximately 600 patients and over half are already included. In this regards please find attached press release that Pharma Mar, S.A. will distribute to the media today”.



## **Phase III trial with Zepsyre® in small-cell lung cancer (ATLANTIS) to continue on the basis of positive recommendation by IDMC**

**Madrid, 15<sup>th</sup> November 2017** – PharmaMar (MSE:PHM) has announced today that the Independent Data Monitoring Committee (IDMC) has notified the Company of its recommendation that the Phase III (ATLANTIS) trial currently under way with Zepsyre® (PM1183) in combination with doxorubicin in small-cell lung cancer patients should continue without any changes.

The IDMC's recommendation came after an analysis of the safety data obtained with the first 150 patients treated in the trial. This pivotal randomised Phase III trial assesses the efficacy of PM1183 in combination compared with the standard treatment for this indication: investigator's choice of either Topotecan or CAV (cyclophosphamide, doxorubicin, and vincristine). The trial is expected to enroll approximately 600 patients and over half are already included.

### **About Zepsyre®**

Zepsyre® is a compound under clinical investigation. It is an inhibitor of RNA polymerase II. This enzyme is involved in the transcription process that is over-activated in tumors with transcription addiction. The antitumor efficacy of lurbinectedin is being investigated in various types of solid tumors, including a Phase III study for platinum-resistant ovarian cancer, a Phase II study for BRCA 1 and BRCA 2-associated metastatic breast cancer and a Phase III study for small cell lung cancer.

### **About small-cell lung cancer**

SCLC is a very aggressive cancer that usually presents with distant metastases and has already spread at the time of diagnosis, thus limiting the role of traditional approaches and posing a worse prognosis compared to other lung cancer types. The 5-year survival rate is about 5%<sup>i</sup>. About 18% of all the lung cancer cases diagnosed are SCLC, and only in the US more than 34,000 new cases are recorded every year. This tumor is strongly associated with tobacco smoking, posing an important public health problem<sup>ii</sup>. After failure to treatment with a platinum-based therapy in first line, the therapeutic alternatives are very limited, and the approval of the last drug for this disease took place 20 years ago.

### **About PharmaMar**

Headquartered in Madrid, PharmaMar is a leading biopharmaceutical company in the discovery and development of innovative marine-derived anticancer drugs. The company has a pipeline of drug candidates and a robust R&D oncology program. PharmaMar develops and commercializes YONDELIS® in Europe and has other clinical-stage programs under development for several types of solid and hematological cancers, Zepsyre® (PM1183), plitidepsin, PM184 and PM14. PharmaMar is a global biopharmaceutical company with subsidiaries in Germany, Italy, France, Switzerland, United Kingdom, Belgium, Austria and the United States. PharmaMar fully owns other companies: GENOMICA, a leading



molecular diagnostics company; Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi); and two other chemical enterprises, Zelnova Zeltia and Xylazel. To learn more about PharmaMar, please visit us at [www.pharmamar.com](http://www.pharmamar.com).

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**Media Contact:**

Alfonso Ortín – Communications Director [aortin@pharmamar.com](mailto:aortin@pharmamar.com) Mobile: + 34609493127  
Paula Fernández – Media Relations Manager [pfalarcon@pharmamar.com](mailto:pfalarcon@pharmamar.com) Mobile: +34 638796215  
Phone: +34 918466000



**Investor Relations:**

Phone: +34 914444500

Or please visit our website at [www.pharmamar.com](http://www.pharmamar.com)

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<sup>i</sup> <http://www.cancer.gov/types/lung/hp/small-cell-lung-treatment-pdq>

<sup>ii</sup> <http://www.jnccn.org/content/11/1/78.full.pdf>