



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

Colmenar Viejo (Madrid), August 31, 2017

Pursuant to article 228 of the restated text of the Securities Market Law, we hereby inform you of the following **SIGNIFICANT EVENT**:

A press release on the forthcoming presentations on scientific studies conducted with Yondelis® and lurbinectedin (PM1183) will be given at the European Society of Clinical Oncology (ESMO) Congress, which will take place in Madrid from the 8<sup>th</sup> to the 12<sup>th</sup> September.



## **PharmaMar will present new clinical data on PM1183 during ESMO 2017**

- *Within the framework of this Congress, favorable data on the efficacy of PM1183 as a single agent and in combination in patients with small cell lung cancer will be presented*
- *With respect to Yondelis®, PharmaMar will present, an indirect, adjusted comparison of trabectedin and pazopanib for the treatment of advanced metastatic leiomyosarcomas*

**Madrid, August 31<sup>st</sup>, 2017.**- PharmaMar (MSE:PHM) will present the clinical data obtained from various clinical studies carried out with its antitumoral compounds of marine origin PM1183 and Yondelis®, during the European Society of Clinical Oncology (ESMO) that will be held from the 8<sup>th</sup> to the 12<sup>th</sup> of September in Madrid, Spain.

The abstract #1529 titled "Activity of lurbinectedin (PM1183) as single agent and in combination in patients with advanced small cell lung cancer (SCLC)" will be presented on September 11<sup>th</sup>. In this abstract, a cohort B will be presented using a new dosing regimen as compared to cohort A that was presented at the American Society of Clinical Oncology Annual Meeting in 2015. The efficacy of PM1183 in this cohort of patients with advanced small cell lung cancer was evidenced by a progression free survival (PFS) of 5.3m with an objective response rate of 37%. The safety profile in Cohort B in terms of the rate of febrile neutropenia, thrombocytopenia and anemia was markedly improved compared to cohort A.

Lurbinectedin is currently enrolling the pivotal phase III ATLANTIS trial in this setting with an expected completion of enrollment around first half of 2018. Dr. Arturo Soto, Director of the Clinical Department at PharmaMar Oncology Business Unit, added "*small cell lung cancer is a devastating disease and the only approved drug for advanced disease is Topotecan. As far as we know these results with lurbinectedin offer the longest PFS seen in this setting and we hope to be able to offer these patients a new treatment option, if we confirm this data in the pivotal clinical trial.*"



Also, during this meeting, PharmaMar will make various presentations in which it will manifest the latest breakthroughs in the clinical development of Yondelis® (trabectedin). A matching, indirect, adjusted comparison of Yondelis® and pazopanib for the treatment of advanced and metastatic leiomyosarcomas; a prospective Phase IV trial that evaluates the use of Yondelis® combined with pegylated liposomal doxorubicin in the clinic to measure the toxicity and the efficacy when it is administered to women with platinum sensitive ovarian cancer, following the marketing authorization (OVA-YOND); along with the observational, prospective study Y-IMAGE, that evaluates the routine, real-life use of trabectedin in patients with advanced soft tissue sarcoma across Europe, as well as a preclinical study on a possible new biomarker to determine the advance of liposarcomas.

The studies that will be presented during this Congress are available on

<https://cslide.ctimeetingtech.com/library/esmo/browse/search>

### **Principle studies that will be presented at ESMO 2017**

#### **PM1183**

- **Activity of lurbinectedin in SCLC (alone and in combination) from different phase I and phase II studies (#1529PD)**

Poster Discussion Session. 11.09.2017, 14:45 - 16:15, Pamplona Auditorium

Lead author: María Eugenia Olmedo, MD, et al. Ramón y Cajal University Hospital, Madrid, Spain

#### **Yondelis® (trabectedin)**

- **A matching-adjusted indirect comparison of trabectedin and pazopanib for the treatment of advanced, metastatic, leiomyosarcomas (#1484PD)**

Poster Discussion Session. 11.09.2017, 11:00 - 12:30, Bilbao Auditorium

Lead author: Robin Jones, MD, et al. Sarcoma Unit, Royal Marsden Hospital, Institute of Cancer Research, London, Great Britain

- **An observational, multicenter, open-label study of trabectedin plus PLD in patients with platinum-sensitive recurrent ovarian cancer (#967P)**

Poster Display Session. 09.09.2017, 13:15 - 14:15, Hall 8

Lead author: D. Reichert, MD et al. Gemeinschaftspraxis für Onkologie, Germany

- **The routine real-life use of trabectedin (T) in patients with advanced soft tissue sarcoma (STS) across Europe: an analysis of overall vs. per country results from Y-IMAGE study (#1499P)**

Poster Display Session. 11.09.2017, 13:15 - 14:15, Hall 8

Lead author: N. Penel, MD et al. Centre Oscar Lambret, Lille, France

- **Outcomes of the combination trabectedin and pegylated liposomal doxorubicin (T-PLD) in recurrent platinum-sensitive ovarian cancer (OC): a GINECO cohort study (#966P)**

Poster Display Session. 09.09.2017, 13:15 - 14:15, Hall 8

Lead author: F. Selle (Paris, France)

- **Geriatric assessment of elderly chemotherapy-naïve patients treated with trabectedin for advanced soft tissue sarcoma: E-TRAB study (#1525TiP)**

Poster Display Session. 11.09.2017, 13:15 - 14:15, Hall 8

Lead author: B. Kasper, MD et al. Interdisziplinäres Tumorzentrum, Universitätsklinikum Mannheim, Germany

- **HMGA1 is a new biomarker of liposarcoma progression (#1689P)**

Poster Display Session. 11.09.2017, 13:15 - 14:15, Hall 8

Lead author: Loria R, MD et al. Cellular network and molecular therapeutic target unit, preclinical models and new therapeutic agents unit

#### **About YONDELIS® (trabectedin)**

YONDELIS® (trabectedin) is a multimodal, synthetically produced antitumor agent, originally derived from the sea squirt, *Ecteinascidia turbinata*. The drug exerts its activity by targeting the transcriptional machinery and impairing DNA repair. It is approved in close 80 countries in North America, Europe, South America and Asia for the treatment of advanced soft tissue sarcomas as a single-agent and for



relapsed ovarian cancer in combination with DOXIL®/CAELYX® (doxorubicin HCl liposome injection) in the European Union. Under a licensing agreement with PharmaMar, Janssen Products, L.P. has the rights to develop and sell YONDELIS® globally except in Europe, where PharmaMar holds the rights, and in Japan, where PharmaMar has granted a license to Taiho Pharmaceuticals.

#### **About PM1183 (lurbinectedin)**

PM1183 is a compound under clinical investigation. It is an inhibitor of RNA polymerase II. This enzyme is essential for 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 PharmaMar**

Headquartered in Madrid, PharmaMar is a world-leading biopharmaceutical company in the discovery and development of innovative marine-derived anticancer drugs. The company has an important pipeline of drug candidates and a robust R&D oncology program. PharmaMar develops and commercializes YONDELIS® in Europe and has three other clinical-stage programs under development for several types of solid and hematological cancers, Zepsyre™ (PM1183), plitidepsin, and PM184. 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, Spain's 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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