



Annual Congress of the American Society of Clinical Oncology (ASCO)

PharmaMar announces encouraging results in clinical trials of lurbinectedin in endometrial and breast cancers

- **The positive results obtained in endometrial cancer with lurbinectedin will be studied in a pivotal phase III study**
- **The Company has agreed the study design with the FDA**
- **The Company has presented at the Congress various clinical studies with inhibitors of activated transcription, Yondelis® and lurbinectedin, in different types of tumors**

Madrid, June 13th, 2017 PharmaMar (MSE:PHM) has participated in the Annual Meeting of the American society of Clinical Oncology (ASCO) with new data with inhibitors of activated transcription, Yondelis® and lurbinectedin.

The Company has presented various studies in different types of tumors, amongst which can be highlighted the results of the study of lurbinectedin in advanced endometrial cancer that showed this molecule is active both as a single agent and when given in combination with doxorubicin ([Link to the abstract](#)).

According to Dr. Arturo Soto, Director of Clinical Development at the Oncology Business Unit at PharmaMar, *"we are very pleased with the positive results obtained in endometrial cancer with lurbinectedin, both as a single agent as in combination with doxorubicin. This favorable data allows us to continue advancing and to set up a pivotal phase III study in agreement with the FDA"*.

Dr Andrés Poveda, Clinical Area of Gynecologic Oncology, Instituto Valenciano de Oncología, Spain, has presented the results of a dose-ranging phase I study that evaluates the safety, tolerability, pharmacokinetics and pharmacodynamics of the combination of lurbinectedin with olaparib in advanced solid tumors, where a synergistic activity between the two molecules has been observed. ([Link to the abstract](#))



PharmaMar also presented a comparison between two different clinical studies that suggests that Yondelis® and lurbinectedin are both more active in BRCA 2 than BRCA 1 metastatic breast cancer. ([Link to the abstract](#))

Other studies to be highlighted at ASCO 2017

PharmaMar has once again demonstrated at the present edition of ASCO 2017 its commitment to contributing innovative solutions to oncological patients from marine based compounds with the characteristics of combating cancer in a novel way.

1. Trabectedin (T) as second line treatment option for patients with epithelioid malignant pleural mesothelioma (MPM) in progression following pemetrexed/platin-derivates chemotherapy: ATREUS trial. (Abstract 8513)

Trabectedin was demonstrated to be effective in terms of progression free survival (PFS) in patients with epithelioid malignant pleural mesothelioma. ([Link to the abstract](#))

2. Correlation between a new growth modulation index (GMI)-based Geistra score and efficacy outcomes in patients (PTS) with advanced soft tissue sarcomas (ASTS) treated with trabectedin (T): A Spanish group for research on sarcomas (GEIS-38 study). (Abstract 11070)

This is a retrospective study carried out by the Spanish Group for Sarcoma Investigation that evaluates the relationship between the Growth Modulation Index, the efficacy results and the clinical profiles of the 190 patients with ASTS. A scale of values called GEISTRA, that allows measurement and the association of the results from the patients has been established as a useful clinical tool for predicting the benefit of trabectedin. ([Link to the abstract](#))

3. Trabectedin and radiotherapy in soft-tissue sarcoma (TRASTS) study: An international, prospective, phase I/II trial—A collaborative Spanish (GEIS), Italian (ISG), and French (FSG) groups study. (Abstract 11061)

This is a European, multicenter, phase I/II prospective study in which the Spanish, Italian and French Sarcoma Groups have collaborated to analyze the combination of trabectedin and radiotherapy during the preoperative



setting. The Phase I results have been presented for patients with centralized and locally advanced myeloid liposarcoma, confirming the combination is feasible and well tolerated, has good pathological results in a high percentage of patients, with a complete pathological response observed in 25% of patients. ([Link to the abstract](#))

4. Trabectedin for advanced soft tissue sarcoma: Ten-year real-life perspective. (Abstract 11060)

This is a retrospective study about real-life experience with trabectedin. The data concludes that this molecule is a safe and effective drug in advanced high grade STS. ([Link to the abstract](#))

5. Phase I study of lurbinectedin (PM11083) in patients with Advanced Myeloid Leukemia (AML) and Myelodysplastic Syndrome (MDS).

In this study, 42 patients with acute myeloid leukemia (AML) and relapsed/refractory myelodysplastic syndrome (MDS) were treated with lurbinectedin with the objective of determining the recommended dose. The results confirm the safety profile and tolerability of lurbinectedin. As a single agent this compound produces a transitory suppressive effect in some patients with leukemia, including some patients with an alteration in the chr11q chromosome or a mutation in the TP53 gene. ([Link to the abstract](#))

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 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, 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.

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