



PharmaMar announces new clinical data on Yondelis® and lurbinectedin (PM1183) to be presented at ESMO 2016

- *Results of an oral presentation will highlight the Phase II clinical trial results with lurbinectedin in patients with BRCA 1/2 metastatic breast cancer*
- *A prospective randomized phase III comparing trabectedin versus the best supportive care in patients with pretreated advanced soft tissue sarcoma (T-SAR trial) will be presented in an oral session by the French Sarcoma Group*

Madrid, October 5th, 2016.- PharmaMar (MSE:PHM) will present new clinical data from its antitumoral compounds of marine origin: Yondelis® (trabectedin) and lurbinectedin (PM1183), at the European Society of Medical Oncology (ESMO) in Copenhagen (Denmark), October 7-11.

Results to be presented in both oral presentations and posters include:

- Single-agent lurbinectedin (PM1183) Phase II trial in patients with BRCA 1/2-associated metastatic breast cancer
- Phase III prospective study carried out in France (T-SAR), which compares trabectedin (Yondelis®) versus the best supportive care in patients with pretreated advanced soft tissue sarcoma (ASTS) to be presented by the French Sarcoma Group

"At this year's ESMO, we will announce the latest breakthroughs obtained with lurbinectedin in multiple tumor types. Through the various clinical trials that PharmaMar is conducting, we can observe that PM1183 shows efficacy both in combination and as single-agent. This gives us potential opportunity for the treatment of solid tumors, including breast and endometrial cancers, among others", stated Dr. Arturo Soto, director of Clinical Development at PharmaMar's Oncology Business Unit.

The trials that will be presented during this congress are available on <https://cslide.ctimeetingtech.com/library/esmo/browse/search>



Highlighted studies at ESMO 2016

Yondelis® (trabectedin)

- **Results of a prospective randomized phase III T-SAR trial comparing trabectedin vs. best supportive care (BSC) in patients with pretreated advanced soft tissue sarcoma (ASTS) (Abstract #1473). Conducted by The French Sarcoma Group**

Proffered paper (Oral presentation). Saturday, October 8th from 11:00 a.m. to 12:15 p.m. Brussels

Lead author: Axel Le Cesne, MD, *et al.* Institut de Cancérologie Gustave Roussy, Villejuif, France

- **Update of the T-DIS randomized phase II trial: trabectedin rechallenge versus continuation in patients with advanced soft tissue sarcoma (Abstract #2368). Conducted by the French Sarcoma Group**

Poster. Monday, October 10th from 13:00 to 14:00 p.m. Hall E.

Lead author: Nuria Kotecki, MD *et al.* Centre Oscar Lambret, Lille, France

Lurbinectedin (PM1183)

- **Anti-tumor activity of PM1183 (lurbinectedin) in BRCA 1/2-associated metastatic breast cancer patients: results of a single-agent phase II trial (Abstract #2333)**

Proffered paper (Oral presentation). Saturday, October 8th from 11:00 to 12:30 p.m. Vienna

Lead author: Judith Balmaña, MD, *et al.* Vall d'Hebron University Hospital and Vall d'Hebron Institute of Oncology, Barcelona, Spain.

- **Phase Ib/II study to evaluate the efficacy and tolerability of PM01183 (lurbinectedin) in combination with olaparib in patients with advanced solid tumors (Abstract #3654)**

Poster. Saturday, October 8th from 13:00 a 14:00 p.m. Hall E.

Lead author: Andrés Poveda, MD, *et al.* Valencia Institute of Oncology. Spain.



- **Lurbinectedin (PM01183) exhibits antitumor activity in PARP-inhibitor resistant germline BRCA PDX and lacks cross-resistance with cisplatin (Abstract # 3003)**

Proffered paper (Oral presentation). Saturday, October 8th from 11:00 to 12:30 p.m. Madrid

Lead author: Cristina Cruz, MD, et al. Vall d´Hebron University Hospital and Vall d´Hebron Institute of Oncology, Barcelona, Spain.

- **Lurbinectedin (PM1183) plus Paclitaxel (P), Recommended Dose (RD) Expansion Results with or without the addition of Bervacizumab (Bev) in patients with selected solid tumors (Abstract #1814)**

Poster. Monday, October 10th from 13:00 to 14:00 p.m. Hall E.

Lead author: A. Drilon, MD, et al. Memorial Sloan Kettering Cancer Centre, New York, USA.

- **Lurbinectedin (PM1183) administered once every 3 weeks in combination with capecitabine in patients with metastatic breast, colorectal or pancreatic cancer (Abstract #2310)**

Poster. Monday, October 10th from 13:00 to 14:00 p.m. Hall E.

Lead author: T. Sauri, MD, et al. Vall d´Hebron University Hospital and Vall d´Hebron Institute of Oncology, Barcelona, Spain.

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, PM1183, plitidepsin, and PM184. PharmaMar is a global biopharmaceutical company with subsidiaries in Germany, Italy, France, Switzerland, United Kingdom, Belgium 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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