

PharmaMar presents positive results from a Phase II study of lurbinectedin in Ewing´s sarcoma at the CTOS International Congress

Madrid, November 13th, 2017. PharmaMar (MSE:PHM) has presented positive results from a Phase II study of lurbinectedin in Ewing´s sarcoma at the Connective Tissue Oncology Society´s (CTOS) International Congress that took place in Hawaii from the 8th to the 11th of November.

In abstract #2768194 entitled "*Efficacy and safety of lurbinectedin (PM1183) in Ewing Sarcoma: results from a Phase 2 study*" the efficacy and safety results from the Phase II basket trial were presented, in which a group of patients with this type of advanced sarcoma, that hadn´t received more than 2 prior chemotherapeutic treatment in metastatic disease, were included. The study is ongoing, although the cohort of patients with Ewing´s sarcoma has now closed.

At the moment of this abstract, 25 patients with Ewing´s sarcoma were enrolled. The observed disease control rate (overall response, partial response and stabilization of the disease) was 60%, including partial responses in 12% of cases, and a stabilization of the disease in the 48% of cases. The observed median duration of response was 2.9 months and 3 months of median progression free survival was reached.

The study showed that adverse effects were generally related to myelosuppression, which were reported to be manageable with dose adjustments. No treatment withdrawals due to toxicity or toxic deaths occurred. The patients with Ewing´s sarcoma have a poor outcome. The authors of the abstract would like to highlight that new therapeutic agents with different mechanism of action are needed, as in the case of lurbinectedin, which has exhibited a favorable safety and tolerability profile as a single agent in pre-treated patients with advanced Ewing´s sarcoma.

Main studies presented at CTOS

- **A matching indirect adjusted comparison of trabectedin and pazopanib for the treatment of advanced, metastatic, leiomyosarcomas. Sponsored by Janssen Research & Development, LLC. And PharmaMar.** Lead author: Robin Jones et al.

- **SAR-3007: Efficacy and safety of trabectedin, when administered as Inpatient vs. Outpatient Site of Care. Sponsored by Janssen Research & Development, LLC.** Lead author: Robin Jones et al.
- **SAR-3007: Genomic Characterization of Uterine Leiomyosarcoma Patients to Define Exploratory Biomarkers in the Phase III Randomized Trial of Trabectedin versus Dacarbazine. Sponsored by Janssen Research & Development, LLC.** Lead author: Gurpreet Kapoor et al.
- **SAR-3007: Efficacy and Safety of Trabectedin in an Elderly Patient Subgroup (≥ 65 years) with Advanced Leiomyosarcoma (LMS) or Liposarcoma (LPS) from the Expanded Access Program (EAP) Sponsored by Janssen Research & Development, LLC.** Lead author: Robin Jones et al.
- **SAR-3002: Efficacy and Safety of Patients Treated Long-Term with Trabectedin (T) on the Expanded Access Program: A Retrospective Analysis Sponsored by Janssen Research & Development, LLC.** Lead author: Elizabeth Davis et al.

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

Lurbinectedin 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 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, Zepsyr® (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.

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