



## PharmaMar begins a Phase I study of PM1183 in Japan for the treatment of solid tumors

**Madrid, November 28th, 2016** – PharmaMar (MSE:PHM) has announced the start of an open-label, multicenter, Phase I study in Japan to evaluate the recommended dose (RD) of PM1183 (lurbinectedin) in patients with certain types of unresectable/advanced solid tumors.

The main objective of the study is to determine the recommended dose of PM1183 in Japanese patients. Furthermore, the secondary objective will be to evaluate the safety profile, to obtain preliminary information on the antitumor activity along with pharmacokinetic characteristics of PM1183 in Japanese patients when compared to Caucasians.

The study population has to be patients born in Japan or descendants from both Japanese parents that suffer disease progression according to the Response Criteria in Solid Tumors (RECIST v1.1).

As Dr Arturo Soto, director of Clinical Development of PharmaMar's Oncology Business Unit, explains *"three clinical sites in Japan will participate in the trial; the number of patients that are to be included will depend on the tolerability and activity observed in PM1183 and the dose level required to identify the recommended dose in this population"*.

### **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, 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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