PharmaMar begins a Phase I study of lurbinectedin in combination with irinotecan for the treatment of solid tumors

Madrid, May 20th, 2016 – PharmaMar (MSE:PHM) has announced the beginning of an open-label, multicenter, Phase I study to evaluate the Maximum Tolerated Dose (MTD) and the Recommended Dose (RD) of lurbinectedin (PM1183) in combination with irinotecan, in patients with selected, advanced solid tumors.

As Dr Arturo Soto, Director of the Clinical Department of PharmaMar´s Oncology Business Unit, explains "*four investigation centers from the US and Europe will participate. The number of patients to be included in the study will depend on the tolerability to the combination of drugs and also on the number of doses that will be needed to reach the MTD. We expect around one hundred patients to be treated with lurbinectedin in combination with irinotecan"*.

It is a prospective, open-label, dose-ranging, uncontrolled Phase I study that, apart from determining the MTD and the RD, also has the objective of analyzing the safety profile, along with the handling of lurbinectedin and irinotecan in the study population; to characterize the pharmacokinetics (PK); to obtain preliminary information on the antitumoral activity of this combination and to evaluate the pharmacogenomics with tumor samples from patients exposed to both compounds in order to assess potential markers to both response and/or resistance.

In the tumor specific expansion cohort(s) which will be performed at the RD, an efficacy assessable patient should have received at least one dose of each drug (lurbinectedin and irinotecan) and have had an evaluation of the disease after treatment.

About lurbinectedin (PM1183)

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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