PharmaMar initiates a phase II “Basket” trial for PM1183 in selected advanced solid tumors

The first patient for the study has been enrolled in the US

Madrid, September 17, 2015: PharmaMar announced today the start of a multicenter, international, open-label, exploratory phase II “Basket” trial (NCT02454972) to evaluate the efficacy and safety of the anticancer agent PM1183 (lurbinectedin) in advanced solid tumors. This “Basket” trial will include patients that have different solid cancers in advanced stages, including small cell lung cancer (SCLC), head and neck cancer, neuroendocrine tumors (NETs), biliary tract tumors, endometrial cancer, BRCA 1/2-associated breast cancer, germ cell tumors and Ewing’s family of tumors as well as other tumors of unknown primary site.

The transcription inhibitor PM1183 will be tested in up to 225 cancer patients in the US and Europe. The primary endpoint will assess the overall response rate (ORR), which is the proportion of patients that have either a complete or partial response, obtained with PM1183 in each of these tumors. The secondary objectives of the study will include endpoints to better characterize the activity of PM1183, such as duration of response, clinical benefit, progression-free survival (PFS) and overall survival at one year. In addition, this study will evaluate the safety and pharmacological profile of PM1183 in these patients, as well as pharmacogenetic and pharmacogenomics analyses to explore individual variability and predictive factors of drug response, respectively.

“This basket trial will help us identify in which advanced cancers with limited or no treatment options, PM1183 will be more effective and will provide valuable data for the therapeutic development of this drug in different tumors,” said Dr. Arturo Soto, Clinical Development Director, PharmaMar.

About PM1183

PM1183 is an investigational drug from the class of inhibitors of the enzyme RNA polymerase II, which is crucially involved in transcription. By targeting transcription, the drug inhibits the expression of factors important for tumor progression, and impairs the DNA repair system called NER, thereby enhancing tumor cell killing. PM1183 (lurbinectedin) is currently being investigated in different tumor types, including a Phase 3 study for platinum-resistant ovarian cancer, a Phase 2 study for BRCA1/2-associated metastatic breast cancer and a Phase 1b study for small cell lung cancer.
About PharmaMar

Headquartered in Madrid, PharmaMar is the world-leading biopharmaceutical company in advancing cancer care through the discovery and development of innovative marine-derived anticancer drugs. The company has a rich pipeline of drug candidates and a robust R&D oncology program. YONDELIS® is the first anticancer drug of marine origin and is commercially available in 81 countries for the treatment of advanced soft-tissue sarcomas as a single-agent, and for relapsed platinum-sensitive ovarian cancer in combination with DOXIL®/CAELYX®. PharmaMar develops and commercializes YONDELIS® in Europe and has three clinical-stage programs under development for several types of solid and hematological cancers, PM1183, plitidepsin, and PM60184. PharmaMar is a global biopharmaceutical company with subsidiaries in Germany, Italy, France, Switzerland and the United States. To learn more about PharmaMar, please visit us at www.pharmamar.com.

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