PharmaMar announces positive results from its Phase II study with lurbinectedin in BRCA 1/2 -associated metastatic breast cancer at the ESMO 2016 Congress

- *The data was presented at an oral session at the European Society of Medical Oncology (abstract #2333)*
- *The study meets its primary objective obtaining an overall response rate (ORR) in 41% of the patients. In the BRCA 2 subgroup, the ORR was 61%, while in those patients with BRCA 1, this was 26%*

Madrid, October 10th, 2016.- PharmaMar (MSE:PHM) has announced the positive results of its Phase II study of lurbinectedin (PM1183) in patients with BRCA 1 / 2 – associated metastatic breast cancer, who had previously received a maximum of 3 prior chemotherapy regimens.

Approximately, 5–10% of breast cancers are associated with the BRCA 1 or 2 hereditary mutations. For the moment the treatment of these patients is similar to any other type of breast cancers, that is mainly conditioned by their hormone receptor and HER2 status. However, recent studies around the mutation demonstrate that these types of tumors behave differently in breast cancer, therefore, the patients harboring these mutations could benefit from a more specific treatment.

Doctor Judith Balmaña, oncology expert from the Vall D´Hebron Institute of Oncology, and principal investigator of the trial, presented the data at an oral session at the European Society of Medical Oncology (ESMO) Congress, being held in Copenhagen, Denmark, that started on the 7th and running to the 11th of October.

The primary endpoint of the trial is to analyze the antitumoral activity of lurbinectedin in this cohort of patients in terms of overall response rate (ORR), according to the Response Evaluation Criteria in Solid Tumors (RECIST V1.1). 54 patients were treated in total and a significant reduction in tumor size was observed in 22 of them (ORR 41%). The primary endpoint of at least 17 responses was comfortably achieved. It is important to emphasize that the ORR of the patients

with BRCA 2 gene mutation subgroup was 61%, while in those patients with BRCA 1 gene mutation, the figure was 26%.

Apart from this parameter, others, such us median duration of response (6.7 months), progression free survival (4.1 months), one year overall survival (15.9 months), and clinical benefit (reduction in tumor lesions, or at least 3 months stability) in 61% of patients were observed.

Throughout the clinical trial, the 7 mg initial dose of lurbinectedin was adjusted to 3.5 mg/m^2, both being administered intravenously every three weeks with the objective of improving the safety profile of the drug.

The investigator´s team, led by Dr Balmaña, arrived to the conclusion that lurbinectedin (PM1183) is an active compound in BRCA associated metastatic breast cancer, even independently of the prior treatment with platinum. With the dose adjustment to 3.5 mg/m^2, the tolerance to the drug was significantly improved, while the compound´s efficacy was maintained.

PharmaMar will continue with the clinical development of this molecule in patients with this type of metastatic cancer, given the clinical results obtained in this Phase II study.

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 BRCA 1 / 2 –associated metastatic breast cancer

Breast cancer is the most frequent form of cancer in women in the Western world[i]. Between 5-10% of breast cancers are associated with the hereditary mutation of the BRCA (BRCA 1 or BRCA 2) gene[i]. It is estimated that bearers of the BRCA 1 / 2 gene mutation run the risk of developing breast cancer during their life of 60-70% and 45-55%, respectively[ii]. Almost 12% of the female population will suffer breast cancer at some stage of their life[iii].

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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