Abstract number #8006

PharmaMar reports positive results from the Phase I study of Aplidin® (plitidepsin) in combination with bortezomib and dexamethasone in patients with multiple myeloma at the 2016 ASCO Annual Meeting

- *The data will be presented in an oral session (abstract #8006)*
- *The conclusions of the study point to a response rate of 56% of the treated patients with 90% of them presenting duration of response (DOR) of six months or more. Seventy two percent of the patients had clinical benefit.*

Madrid, May 19th, 2016.- PharmaMar (MSE:PHM) announces the positive results from a Phase I study of Aplidin® (plitidepsin) in combination with bortezomib and dexamethasone in patients with relapsed and/or refractory multiple myeloma. Dr María Victoria Mateos, MD of the Hematological Department of the University Hospital of Salamanca, Spain, the principal investigator of the study, will present the results in an oral session on June 3rd, 2016 during the 52nd Congress of the American Society of the Clinical Oncology (ASCO), taking place in Chicago (USA), June 3 – 7.

The primary objective of this 20-patient study was to identify the recommended dose for the triple combination (dexamethasone / bortezomib / plitidepsin) administered every four weeks. Efficacy and the safety profile were also evaluated. The overall response rate (ORR) was 56%, including very good partial responses (VGPR) in 33% of the patients and a remarkable partial remission in one triple refractory patient. The median progression free survival (PFS) was 8.3 months. Additionally, 90% of the patients showed a DOR of 6 months or more and clinical benefit was observed in 72% of the patients.

Dose limiting toxicities were not seen in any of the evaluated patients; therefore, the full dose of plitidepsin and bortezomib when used alone were established as the recommended dose for the triple combination. The treatment was well tolerated.

The hematological toxicity was manageable and the non-hematological toxicity was in general mild, with the exception of one case of creatinine increase.

Out of the 20 patients that participated in the study, 10 are still under the treatment. The median age was 65. All patients had relapsed after previously receiving, on average, 3.5 therapeutic regimens (range 1-10). Forty-five percent of these patients had been subject to a hematopoietic stem cell transplant (8 autologous, 1 allogeneic). Of the 18 patients evaluable for efficacy, 83% (15 patients) had previously received bortezomib and lenalidomide. One was refractory to bortezomib and seven to lenalidomide.

In abstract #8006, Dr María Victoria Mateos and her team explain that despite the recent progress in the treatment of multiple myeloma due to the introduction of proteasome inhibitors (PIs), the new immunomodulatory drugs (IMIDs), and monoclonal antibodies, the illness is still incurable. Therefore, active compounds with novel mechanisms of action and adequate safety profile are needed. Plitidepsin targets the eukaryotic Elongation Factor eEF1A2, an overexpressed protein in multiple myeloma that contributes to its pathogenesis. The positive results from this study will be added to the already extensive data package from Phase II and Phase III trials, where Aplidin® (plitidepsin) has shown activity and a favorable safety profile in combination with dexamethasone.

About multiple myeloma

Multiple myeloma is a relatively uncommon type of blood cancer, which accounts for 10% of all hematological malignancies, this being caused by malignant plasma cells that very rapidly multiply[i]. Normal plasma cells are white blood cells, which form part of the immune system, found in the bone marrow that produces the antibodies necessary for fighting infections[ii]. Abnormal cells produce a type of antibody that does not benefit the body and accumulate, thus preventing normal cells from functioning properly. Almost all patients with multiple myeloma progress from an initial, asymptomatic pre-malignant stage to established disease. In 2015, 26,850 new cases were diagnosed in the US, and about 11,200 people died from this disease[iii].In Europe, the incidence is 4.5–6.0 out of 100 000 diagnosed per year[iv].

About plitidepsin

Plitidepsin is an investigational anticancer agent of marine origin, originally obtained from the ascidian Aplidium albicans. It is thought that it specifically binds to the eEF1A2 and targets the non-canonical role of this protein, resulting in tumor cell death via apoptosis (programed

death). Plitidepsin is currently in clinical development for hematological cancers, including a PhaseIb trial in relapsed or refractory multiple myeloma as a triple combination of plitidepsin, bortezomib and dexamethasone, and a Phase II study in relapsed or refractory angioimmunoblastic T-cell lymphoma. A Phase III trial in relapsed or refractory multiple myeloma has been completed. Plitidepsin has received orphan drug designation both in the EU and the US.

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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[i] http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-it

[ii] http://www.myeloma.org.uk/information/what-is-myeloma/

[iii] http://seer.cancer.gov/statfacts/html/mulmy.html

[iv] http://www.esmo.org/Guidelines/Haematological-Malignancies/Multiple-Myeloma