PharmaMar submits MAA to EMA for Aplidin® for the treatment of multiple myeloma

- **The Company estimates that the feedback from the EMA could be in the second half of 2017**
- **PharmaMar will receive from its license holders 4 million euros for the presentation of this marketing authorization**

Madrid, September 22nd, 2016 – PharmaMar (MSE:PHM) has announced today the submission to the European Medicines Agency (EMA) of the Marketing Authorization Application (MAA) for Aplidin® (plitidepsin) in combination with dexamethasone for the treatment of relapsed/refractory multiple myeloma (MM). This is a type of blood cancer which represents 10% of all hematological malignancies.

PharmaMar has gone through with this application given the positive data obtained from the randomized, Phase III ADMYRE clinical trial, where the efficacy and safety of Aplidin® with dexamethasone versus dexamethasone alone in patients with relapsed/refractory MM after at least three, but no more than six, prior therapeutic regimens has been evaluated. The results of the ADMYRE study showed a statistically significant 35% reduction in the risk of progression or death over the comparator. The study met its primary endpoint.

The submission of this MMA to the EMA represents an important milestone for PharmaMar. *"We have achieved positive results with this molecule throughout its clinical development and we believe Aplidin® could become a novel therapeutic alternative for patients with multiple myeloma",* says Luis Mora, Managing Director of PharmaMar´s Oncology Business Unit, who also adds *"that we estimate the answer from the regulatory agency for the second half of 2017".*

Aplidin® has received orphan drug designation by the European Commission and the US Food and Drug Administration (FDA). Up to today, PharmaMar has various licensing agreements for the sales and distribution of this compound with Specialised Therapeutics Asia PTE Ltd. (Singapore) in several countries for

Southeast Asia, Australia and New Zealand; with TTY Biopharm in Taiwan; and with Chugai Pharma Europe Ltd. in 8 European countries.

PharmaMar will be paid by Chugai Pharma Europe Ltd. 4 million euros for the presentation of the above mentioned MAA.

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 produce 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. 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], and the prevalence is 18 cases per 100 000 diagnosed over five years[v].

About APLIDIN® (plitidepsin)

Plitidepsin is an investigational anticancer agent of marine origin, originally obtained from the ascidian *Aplidium albicans*. 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 Phase Ib 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. Plitidepsin has received orphan drug designation in the European Union and the United States of America.

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
[v] GLOBOCAN 2012, IARC - 6.9.2016