Aplidin® shows positive results in pivotal Phase III clinical trial for multiple myeloma

- **PharmaMar intends to submit a Marketing Authorization Application to the European Medicines Agency during the last quarter of this year**

Madrid, 31st of March, 2016 – PharmaMar (MSE:PHM) today announced positive top-line results of its Phase III clinical trial -ADMYRE- with Aplidin® (plitidepsin) in combination with dexamethasone versus dexamethasone alone in patients with relapsed/refractory multiple myeloma (MM). Aplidin® has shown a statistically significant 35% reduction in the risk of progression or death over the comparator (p=0.0054). The study has met its primary endpoint.

This pivotal, randomized, open-label, international, multicenter Phase III clinical trial, called ADMYRE, enrolled 255 patients in 83 medical centers across 19 countries (including the U.S, Europe and Asia-Pacific) with relapsed or relapsed and refractory multiple myeloma after at least three but no more than six prior therapeutic regimens.

The efficacy of plitidepsin in combination with dexamethasone versus dexamethasone alone has been evaluated by means of PFS calculated using the IMWG (International Myeloma Working Group) criteria and other secondary efficacy endpoints. A full description of the final ADMYRE data will be submitted for presentation at an upcoming medical meeting.

"Taking into account these positive results, we intend to submit a Marketing Authorization Application to the European Medicines Agency during the last quarter of this year", said Luis Mora, Managing Director of the Oncology Business Unit of PharmaMar, who added *"I´d like to thank all the patients, physicians and the dedicated team at PharmaMar who helped participate in the success of this trial. Aplidin® may be our second drug of marine origin in the market".*

As previously disclosed PharmaMar has entered into licensing agreements to market and distribute the drug candidate Aplidin® with Specialised Therapeutics Asia, covering several Asian countries, Australia and New Zealand; with TTY Biopharm in Taiwan; and with a co-promotion agreement in 8 European countries with Chugai Pharma Europe.

About multiple myeloma

Multiple myeloma is a relatively uncommon type of blood cancer, which accounts for 10% of all hematological malignancies, that is 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 to fight 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 of this disease[iii].In Europe, the incidence is 4.5–6.0 out of 100 000 diagnosed per year[iv].

About APLIDIN® (plitidepsin)

Plitidepsin is an investigational anticancer agent of marine origin, originally obtained from the ascidian *Aplidium albicans*. It is a first-in-class drug specifically targeting eEF1A2 in tumor cells. Plitidepsin is currently in clinical development for hematological cancers, including this Phase III study in relapsed or refractory multiple myeloma, 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 by the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA).

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 other three 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