The EMA accepts to assess the Marketing Authorization Application from PharmaMar for Aplidin®

Madrid, October 28th, 2016 – PharmaMar (MSE:PHM) has announced today that the European Medicines Agency (EMA) has accepted to assess the Marketing Authorization Application (MAA) for Aplidin® (plitidepsin) in combination with dexamethasone for the treatment of relapsed/refractory multiple myeloma (MM).

PharmaMar submitted the above mentioned application for the antitumor drug of marine origin, Aplidin®, in combination with dexamethasone given the positive results obtained from the ADMYRE study. Plitidepsin could be a therapeutic alternative for patients suffering from relapsed and/or refractory multiple myeloma.

After this acceptance, the EMA is going to start the assessment of this potential treatment for a type of blood cancer which accounts for 10% of all hematological malignancies.

The ADMYRE clinical trial is a randomized, Phase III study 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.

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