PharmaMar completes patient recruitment of Phase III registration trial (ADMYRE) with APLIDIN® (plitidepsin) in multiple myeloma

The pivotal study will assess the efficacy of plitidepsin plus dexamethasone versus dexamethasone alone in patients with relapsed/refractory multiple myeloma

Madrid, June 1st, 2015 - PharmaMar announced today that the patient recruitment for the pivotal Phase III trial of APLIDIN® (plitidepsin) for the treatment of multiple myeloma, denominated ADMYRE, has been successfully completed. The study, which originally planned to include 250 patients, has enrolled 255 patients in 71 medical centers worldwide, including the US, Europe, Asia, Australia, and New Zealand. An application for marketing authorization in Europe is planned to be submitted in 2016.

ADMYRE is a prospective, pivotal, randomized (2:1), open-label, multicenter study that compares plitidepsin in combination with dexamethasone versus dexamethasone alone in patients who have relapsed or refractory multiple myeloma after at least three prior therapies, but no more than six. Patients must have previously received bortezomib and lenalidomide. In an interim analysis, the Independent Data Monitoring Committee (IDMC) recommended completion of the Phase III ADMYRE unmodified given that no safety issues were reported and the study comfortably met the established efficacy threshold upon evaluation of data from 60 evaluable patients[i].

In this registration trial, the primary endpoint is progression-free survival (PFS), which will be used to compare the efficacy of plitidepsin plus dexamethasone versus dexamethasone alone. Secondary endpoints will evaluate tumor response rate, duration of response and overall survival.

"Our compound represents a first-in-class drug in the therapeutic paradigm of multiple myeloma" said José María Fdez. Sousa-Faro, PhD, Chairman of PharmaMar. "We are on track now to bring this innovative therapeutic advance a step closer to these patients."

About multiple myeloma

Multiple myeloma is a relatively uncommon type of blood that accounts for 10% of all hematological

malignancies and that is caused by malignant plasma cells that very rapidly multiply[ii]. Normal plasma cells are white blood cells found in the bone marrow that form part of the immune system and produce the antibodies necessary to fight infections[iii]. 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 will be diagnosed in the US, and about 11,200 people will die of this disease[iv].In Europe, there will be 4.5–6.0 out of 100 000 people diagnosed per year[v].

About APLIDIN® (plitidepsin)

Plitidepsin is an investigational anticancer agent of marine origin, originally obtained from the tunicate Aplidium albicans. It specifically binds to the eEF1A2 and targets the non-canonical role of this protein, resulting in tumor cell death via apoptosis (programmed death). Plitidepsin is currently in clinical development for hematological cancers, including a 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 Drud Administration (FDA)

About PharmaMar

Headquartered in Madrid, PharmaMar is the world-leading biopharmaceutical company in advancing cancer care through the discovery and development of innovative marine-derived anticancer drugs. The company has a rich pipeline of drug candidates and a robust R&D oncology program. YONDELIS® is the first anticancer drug of marine origin and is commercially available in 81 countries for the treatment of advanced soft tissue sarcomas as a single-agent, and for relapsed platinum-sensitive ovarian cancer in combination with DOXIL®/CAELYX®. PharmaMar develops and commercializes YONDELIS® in Europe and has three clinical-stage programs under development for several types of solid and hematological cancers, PM1183, plitidepsin, and PM60184. PharmaMar is a global biopharmaceutical company with subsidiaries in Germany, Italy, France, Switzerland and the United States. To learn more about PharmaMar, please visit us at www.pharmamar.com.

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[i] http://www.pharmamar.com/en/press/pharmamar%E2%80%99s-aplidin%C2%AE-phase-3-admyre-trial-relapsed-refractory-multiple-myeloma-achieves
[ii] http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-it
[iii] http://www.myeloma.org.uk/information/what-is-myeloma/
[iv] http://seer.cancer.gov/statfacts/html/mulmy.html
[v] http://www.esmo.org/Guidelines/Haematological-Malignancies/Multiple-Myeloma