



PharmaMar announces the start of a pivotal study with plitidepsin in angioimmunoblastic T-cell lymphoma

- *The primary endpoint is to analyze the efficacy of plitidepsin in the type of hematological cancer, angioimmunoblastic T-cell lymphoma, which is classified as a rare disease.*

Madrid, June 14th, 2016 – PharmaMar (MSE:PHM) today announced the start of a multicenter, prospective, pivotal study to analyze the efficacy of the antitumoral compound of marine origin, plitidepsin in patients with relapsed and refractory angioimmunoblastic T-cell lymphoma. As this is classified as a rare disease, and in consultation with the US Food and Drug Administration (FDA), the study has been designed with only one study arm.

The primary objective is to analyze the efficacy of plitidepsin in terms of overall response rate, to be evaluated by an independent committee following the Lugano classification response criteria. The secondary endpoint will be to evaluate other efficacy parameters such as duration of response, progression free survival and overall survival; the pharmacokinetic characteristics, the safety profile of plitidepsina and the identification of possible biomarkers that help to identify the predictive activity of the compound.

"This pivotal clinical trial will include 60 patients from approximately 25 investigative sites", stated Dr Arturo Soto, Director of Clinical Development at PharmaMar's Oncology Unit. *"After the recent announcement of the positive results obtained with plitidepsin in patients with multiple myeloma, we are continuing with the development of this molecule in other hematological tumors such as angioimmunoblastic T-cell lymphoma".*

About 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 mieloma 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 multiple myeloma relapsed or refractory has been completed. Plitidepsin has received orphan drug designation in the European Union and the United States of America.

About T-cell lymphoma

Lymphoma is the most common blood cancer. Angioimmunoblastic Lymphoma is a fast-growing T-cell lymphoma accounting for 15 percent to 18 percent of all T-cell lymphomas in the United States. Initial symptoms often include swollen lymph nodes and systemic symptoms such as fever and rash. It is generally treated like other fast-growing T-cell lymphomas, but can be managed with milder therapies in certain circumstances¹.

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.lymphoma.org/site/pp.asp?c=bkLTKaOQLmK8E&b=6300161>