



## **Aplidin<sup>®</sup> receives orphan drug status for the treatment of multiple myeloma in Switzerland**

- **Pharma Mar S.A. submitted the Marketing Authorisation Application in the European Union at the end of 2016**

**Madrid, May 4, 2017.-** PharmaMar (PHM:MSE) announces that Aplidin<sup>®</sup> has been granted orphan drug status by the Swiss Agency for Therapeutic Products (Swissmedic) for the treatment of patients with multiple myeloma.

This decision has been based, on the one hand, for the recognition as an orphan drug granted by the European Commission, as by the Food and Drug Administration (FDA) in 2004, and, on the other hand, by the data provided to the agency relating to efficacy, safety, quality of the drug and prevalence of the disease.

*"This authorisation is an important milestone in the treatment of multiple myeloma, recognizing that Aplidin<sup>®</sup>, with its novel mechanism of action, could become a therapeutic alternative",* explains Luis Mora, Managing Director of the Oncology Business Unit at PharmaMar.

Orphan drug designation in the European Union and Switzerland is given to compounds that are developed for the treatment of diseases that affect 5 out of every 100,000 inhabitants. This designation provides the sponsor with a series of incentives, amongst which are included the possibility of a priority review by Swissmedic, the competent authority in Switzerland.

### **About APLIDIN<sup>®</sup> (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. 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 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, Austria 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](http://www.pharmamar.com).

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