



## **PharmaMar submits the Marketing Authorisation Application for Aplidin® in Switzerland**

- **Pharma Mar S.A. submitted the Marketing Authorisation Application in the European Union at the end of 2016**
- **The regulatory process for oncological products in Switzerland is independent from the European Medicines Agency (EMA)**

**Madrid, October 4<sup>th</sup>, 2017.-** PharmaMar (PHM:MSE) announces submission of the Marketing Authorisation Application to the Swiss Agency for Therapeutic Products (Swissmedic) for Aplidin® for the treatment of patients with multiple myeloma.

The regulatory process for an oncological drug in Switzerland is independent from that of the European Medicines Agency's process (EMA), to which PharmaMar submitted the corresponding application at the end of 2016.

Aplidin® was designated orphan drug status by Swissmedic, the European Commission and also the Food and Drug Administration (FDA). In the European Union, this status is granted for the compounds that are investigated for the treatment of illnesses that affect 5 per 10,000 inhabitants or less. This gives the sponsor a series of incentives, among which are included the possibility of a priority evaluation by Swissmedic, the regulatory authority in Switzerland.

The submission of this application represents a milestone for PharmaMar. *"We have obtained positive results with this molecule in the pivotal phase III study and we believe that Aplidin® could be a novel therapeutic alternative for patients with multiple myeloma that live in Switzerland"*, says Luis Mora, Managing Director at the Oncology Business Unit at PharmaMar.

### **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 and bortezomib, and a Phase II in patients with multiple myeloma refractory to lenalidomida and bortezomib. Furthermore, 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, Zepsyre™ (PM1183), plitidepsin, PM184 and PM14. 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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