FDA chooses Zepsyre™ (PM1183) from PharmaMar to explore potential development for pediatric cancers

- This is one of the three molecules chosen by the Oncologic Drugs Advisory Committee (ODAC) of the FDA to evaluate its activity in this field.
- Zepsyre™ (lurbinectedin) is in the latter stages of development in various tumors for adults.

Madrid, June 20th, 2017.- The Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee (ODAC) of the FDA, has invited PharmaMar to participate in this ODAC, giving a presentation to provide background information on Zepsyre™, positive clinical data obtained from phases I and II, in which a good tolerance and a good safety profile were observed, and to assess the potential role of this drug in pediatric cancers and hematological disorders.

Zepsyre™ (PM1183), PharmaMar´s investigational drug, is one of the three products chosen by ODAC.

The subcommittee will consider and discuss with PharmaMar issues concerning the diseases to be studied, patient populations to be included and possible study designs in the development of this product for pediatric use. The discussion will also provide the FDA with guidance to facilitate formulation of Written Requests for pediatric studies, if appropriate.

According to Luis Mora, Managing Director of the Oncology Unit at PharmaMar, *"we are pleased to have been chosen to participate in the Pediatric Subcommittee meeting. Given the mechanism of action of Zepsyre™ as well as the available clinical data from phases I and II, in which we observed a good tolerance and a good safety profile, we believe that there may be potential relevance for PM1183 to be developed in one or more pediatric cancers. PharmaMar is a willing participant at this meeting and we hope it is going to be helpful for patients and investigators as well as the FDA".*

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.

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