



## PharmaMar initiates a Phase II trial with antitumour drug PM184 in advanced breast cancer

**Madrid, 26, February 2016** – PharmaMar (MSE:PHM) has announced the start of an open-label multi-centre two-stage Phase II trial with the anti-tumour drug PM184. The trial will be conducted in 10 European clinical centres and will include 106 patients. The trial will focus on patients with hormone-receptor positive, HER2-negative, locally advanced and/or metastatic breast cancer, who have experienced progression following earlier treatment with anthracyclines and taxanes. The second stage of this Phase II trial will be randomised vs. investigator's best choice, to assess the efficacy and safety of PM184.

The primary endpoint is to evaluate the efficacy of PM184 with regard to four-month progression free survival (PFS). Secondary endpoints include analysing a more convenient administration pattern for PM184, overall survival, median PFS, overall response, and response duration measured in accordance with RECIST (Response Evaluation Criteria In Solid Tumors) Guideline Version 1.1. The trial will also assess safety and pharmacological profiles in the target population, and perform pharmacogenetic analyses to examine inter-patient variations in the transformation and elimination of PM184, together with pharmacogenomic studies that will contribute to identifying predictors of the response to the drug.

*"We are encouraged that PM184 is now progressing into Phase II clinical trial which represents a significant step forward by PharmaMar in addressing breast cancer, one of the most common cancers,"* said Arturo Soto, Director of Clinical Development at PharmaMar's Oncology Unit. *"PM184 is a compound of marine origin that inhibits the microtubular function and targets a protein called tubulin in a novel way, and we are very looking forward to the results,"* he added.

### **PM184**

PM184 is a marine-derive drug found in a sponge called *Lithoplocamia lithistoides*. This drug candidate is a microtubule inhibitor that targets a protein called tubulin in a novel way. It blocks cancer growth by impairing cell division of tumor cells through the inhibition of a crucial process called mitosis. It is in early-stage development and is currently being investigated in phase I studies in various solid tumors.

### **Breast cancer**

Breast cancer is the most frequent form of cancer among women in the Western countries<sup>1</sup>. Approximately 232,340 new cases were detected in the US in 2013, and it caused 39,620 deaths in that



year.<sup>ii</sup> The number of cases is expected to increase by 50% by 2030. Despite progress with treatment, close to 30% of women who are diagnosed in the early stages of breast cancer experience progression to a recurrent or advanced form of the disease. Average survival for patients with metastatic or advanced breast cancer is 18-30 months.

#### **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 other three 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](http://www.pharmamar.com).

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<sup>ii</sup> DeSantis C, Ma J, Bryan L, Jemal A. Breast Cancer Statistics, 2013. CA: a cancer journal for clinicians. 2014 Jan-Feb;64(1):52-62.